UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

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OPTN/UNOS Policy and Bylaw Proposals

Distributed for Public Comment

September 29, 2014

This document contains eighteen proposals being offered for public comment. These proposals were developed by OPTN/UNOS committees. When the public comment period ends on **December 5, 2014,** each sponsoring committee will review the feedback it received and consider modifications to the original proposals. The OPTN/UNOS Board of Directors may then review and vote on these proposals at its meeting on **June 1-2, 2015.**

Please click on the following link to provide your comments on these proposals:
http://optn.transplant.hrsa.gov/governance/public-comment/

You may also continue to send general feedback to publiccomment@unos.org.

Please submit all comments no later than **December 5, 2014.** . For general questions about the proposals, please contact your Regional Administrator at (804) 782-4800.

We welcome your feedback on these proposals and other aspects of the public comment process as we continue to improve the way that we communicate with the community.

Thank you in advance for your careful review and feedback on these proposals.

UNOS and the OPTN: Getting Involved in the Public Comment Process

Under contract with the U.S. Department of Health and Human Services' Health Services and Resources Administration (HRSA), the United Network for Organ Sharing (UNOS) coordinates the nation's organ transplant system, providing vital services to meet the needs of men, women and children awaiting lifesaving organ transplants. UNOS unites transplant professionals and organ procurement specialists throughout the nation to match transplant candidates with the organs they need. This nationwide system is called the Organ Procurement and Transplantation Network (OPTN).

The field of organ transplantation depends on the cooperation of many people and organizations, and it is vital to ensure the opinions of all interested parties are heard and addressed. Therefore, the OPTN strives to achieve consensus in the development of policies that determine how organs are allocated throughout the nation.

Committees within the OPTN review transplant data and issues and periodically may draft a new or revised policy to address a particular issue. Before going to the OPTN/UNOS Board of Directors for a vote, UNOS publishes all substantial policy proposals for public comment by other committees, OPTN/UNOS regions and interested persons or organizations. The sponsoring committee will consider all comments received before it makes a final recommendation to the board. The board then considers policy proposals in light of the input received.

Final decisions about policy proposals are published on the OPTN and UNOS web sites. A policy notice detailing all board-approved policy changes is sent to OPTN/UNOS members and other interested parties approximately 30 days after the board meeting. This notice includes all implementation dates that are available at the time of publication.

Input from transplant candidates – the people most affected by new or revised policy – is an important part of the public comment process. The OPTN strongly encourages all interested individuals – especially transplant candidates – to express their views on policy proposals by getting involved in the public comment process.

You can view proposals that go out for public comment several ways. You can visit the OPTN and UNOS web sites directly at www.optn.org or www.unos.org, or you can send an e-mail to publiccomment@unos.org and sign up to receive e-mail notification of future documents. If you are unable to access the Internet, you can receive a paper copy of the document by calling or faxing a request to the UNOS public comment coordinator. You may also submit a written request to UNOS.

For more information, please contact:

Public Comment Coordinator
United Network for Organ Sharing
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Specific questions about policy proposals can be answered by the UNOS Regional Administrator for your area. Please consult the listing below to determine your regional contact person.

Shannon Edwards (shannon.edwards@unos.org)
Region 1 - Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont
Region 4 - Oklahoma, Texas
Region 9 - New York, Western Vermont

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Region 6 - Alaska, Hawaii, Idaho, Montana, Oregon, Washington
Region 8 - Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming

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Region 5 - Arizona, California, Nevada, New Mexico, Utah
Region 7 - Illinois, Minnesota, North Dakota, South Dakota, Wisconsin
Region 10 - Indiana, Michigan, Ohio

Table of Contents

I. Summary of Public Comment Items

Summary of Public Comment Proposals Distributed September 29, 2014

1. Proposal for Informed Consent for Kidney Paired Donation (Kidney Transplantation Committee)

The *Proposal for Informed Consent for Kidney Paired Donation* proposes required elements for informed consent for paired candidates and donors participating in any KPD program. The proposal requires transplant programs registering the paired candidates and donors to inform KPD participants of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process, including prioritization information and consequences of shipping kidneys. It also includes additional informed consent elements for non-directed donors (NDDs) and bridge donors participating in any KPD program. These informed consent requirements are intended to be supplemental and additional to the requirements required in Policy 14.3: Informed Consent Requirements.

2. Proposal to Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy (Kidney Transplantation Committee)

In June 2014, the OPTN/UNOS Board of Directors approved the removal of the "pilot" label from the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP). Though the "pilot" label will not be removed until the Board's decision is approved by the Health Resources and Services Administration (HRSA), the Kidney Committee believes it is appropriate to continue to transition sections of the operational guidelines into OPTN policy. Including these sections in OPTN policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN. Other sections of the operational guidelines were previously transitioned to OPTN policy in November 2012 and June 2014.

3. Proposal for the Definition of Pancreas Graft Failure (Pancreas Transplantation Committee)

Currently, there is no nationally and consistently utilized definition for how to identify and document pancreas allograft failure. Pancreas transplant programs reporting when a pancreas graft failed varies due to no standard definition, and thereby, limits the ability to analyze and compare pancreas programs' outcomes.

The proposal's purpose is to draft policy that assists transplant professionals to identify when pancreas allograft failure occurs and how to document the pancreas graft failure event. The proposal achieves this purpose by drafting policy for when a pancreas graft failed, updating Tiedi help documentation surrounding how to document pancreas graft failure, and updating the graft status section in the pediatric and adult pancreas and kidney-pancreas OPTN Recipient Registration and Recipient Follow-Up forms. (Unless otherwise noted, "OPTN pancreas forms" refers to the adult and pediatric pancreas and kidney-pancreas Transplant Recipient Registration Form (TRR) and Transplant Recipient Follow-up Form (TRF) throughout the proposal.)

The Pancreas Transplantation Committee (the Committee) understands the essential and urgent need to measure, and thereby manage outcomes. Although the proposed changes are a significant step forward in the effort for transplant professionals to consistently identify and document pancreas graft failure on a national basis, the Pancreas Transplantation Committee acknowledges the proposed language has room for growth. Currently, the OPTN has not required consistently reporting data necessary to identify and document pancreas graft failure, in every potential scenario, at a national level. As such, the Committee decided to respond to

the imminent need with this proposal and believes this proposal is a significant first step in achieving consistent identification and documentation of pancreas graft failure throughout the U.S. In turn, creating a foundation for which transplant programs may be monitored and managed.

4. Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates (Thoracic Organ Transplantation Committee)

Extracorporeal membrane oxygenation (ECMO) has become a more common treatment for patients with end-stage lung disease awaiting lung transplantation. However, the Thoracic Committee has been unable to consider the impact of ECMO support on lung allocation because this information is not routinely collected and reported to the OPTN. The Thoracic Committee proposes the collection of ECMO information at the time of waiting list removal to retrospectively capture each candidate's mechanical ventilatory support history. This will provide the Thoracic Committee with data on a contemporary cohort of candidates in order to appropriately analyze how ECMO should be incorporated into the LAS calculation.

5. Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs) (Vascularized Composite Allograft Transplantation Committee)

This proposal updates existing OPTN policy and bylaw language and establishes new requirements to add Vascularized Composite Allografts (VCAs) to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN). The proposed policies outline the following:

- Definition of covered body parts in any policies specific to VCA transplantation,
- VCA transplant program membership criteria,
- Allocation of VCA organs,
- Authorization for VCA organs distinct from other whole organ transplants, and
- Other policy and bylaw modifications that would specifically exempt applicability to VCA transplantation

6. Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs) (Vascularized Composite Allograft Transplantation Committee)

The proposed updates to OPTN Policies 18.1 and 18.2 add specific data submission requirements for VCA candidates and recipients, including VCA candidate registration, transplant recipient, and follow-up information. Additionally, VCA-specific data elements have been identified for collection at the time of transplant and follow-up. The intervals for data collection were drawn from those intervals for other organ-specific Tiedi® forms. As an interim solution, VCA candidate/recipient data will be collected outside of DonorNet®, WaitlistSM, and Tiedi®. The database(s) used to collect this information will be managed by UNOS and can be queried to assess member compliance with OPTN policies and bylaws.

7. Improving the OPTN Policy Development Process (Executive Committee)

This proposal includes changes to the OPTN Bylaws intended to improve the OPTN policy development process and provide the OPTN/UNOS Board of Directors and committees more flexibility in addressing different types of problems identified by the transplant community. The proposal includes the creation of two new policy development tracks designed to allow the OPTN/UNOS Board to address emergency and non-controversial issues in a more efficient and expedient manner, while continuing to maintain the OPTN's cornerstone principles of transparency and community consensus.

8. Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II) (Histocompatibility Committee)

This proposal represents the second phase of a comprehensive review of the OPTN Bylaws governing histocompatibility laboratories. This proposal contains numerous proposed changes, including a reference update to the requirement that histocompatibility laboratories maintain the standards of the American Society for Histocompatibility and Immunogenetics (ASHI) or the requirements listed in the College of American Pathologists (CAP) checklists as of a date certain, the addition of general supervisor to laboratory key personnel, modifications of education, certification, and experience requirements for laboratory key personnel, and new performance indicators that will trigger mandatory performance review of a laboratory.

9. Proposal to Establish a Quality Assurance and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations (OPO Committee)

The Membership and Professional Standards Committee (MPSC) has noted that members having difficulty with compliance or performance often do not have well-developed quality assurance and performance improvement (QAPI) programs. Currently, OPTN bylaws do not require that members establish and implement a QAPI program. Motivated by this observation, the MPSC proposes modifications to OPTN Bylaws that require members to implement a QAPI program that must include certain essential elements that are outlined in the proposed Bylaws. A requirement that members develop and implement a comprehensive QAPI program should assist members in their efforts to improve performance and to remain in compliance with OPTN obligations.

10. Definition of a Transplant Hospital (Membership and Professional Standards Committee)

The proposed changes to the transplant hospital definition are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when assessing applicant submissions for OPTN membership and transplant program designation. A transplant hospital member is currently defined by OPTN Bylaws as "a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ" and by OPTN Policy as "a health care facility in which transplants of organs are performed". A lack of distinguishing detail in the transplant hospital definition has proven to be problematic when assessing for membership healthcare institutional configurations consisting of multiple "hospitals" performing the same organ transplants at geographically separated sites. Therefore, the goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance concerning patient safety, patient outcomes, and overall compliance with approved OPTN directives.

11. Proposal to Implement Pre-Transplant Performance Review by the Membership and Professional Standards Committee (Membership and Professional Standards Committee)

Currently, transplant program performance monitoring relies almost exclusively on risk-adjusted graft and patient survival rates among recipients. The overemphasis on post-transplant metrics may result in risk-aversion and decreased transplant volumes, and is not in the best interest of waitlisted patients. Further, post-transplant outcomes may not identify structural problems (e.g., understaffing) that prevent a program from keeping up with the needs of its waitlist population. As such, a more holistic approach to performance monitoring is necessary.

The purpose of this proposal is to provide the MPSC with a tool, the Composite Pre-transplant Metric (CPM), for identifying kidney and liver programs that may be in need of review based

on outlying performance in accepting deceased donor organ offers, transplanting waitlisted patients, and/or mitigating waitlist mortality. The CPM is an aggregate, pre-transplant performance metric that combines programs' acceptance rate, geography-adjusted transplant rate, and waitlist mortality rate observed-to-expected (O/E) ratios into a single number for prioritizing programs for potential review.

12. Proposal to Reduce the Reporting Requirements for the Deceased Donor Registration Form (Organ Procurement Organization (OPO) Committee)

Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased donors. This must be completed within 30 days after the deceased donor feedback form is submitted. Due to inconsistent data reporting on those potential donors that do not proceed to donation, the OPO Committee is proposing that the requirement to complete the DDR for non-donors be removed from policy. The goal of this proposal is to reduce the data reporting requirements for "non-donors" by only requiring the completion of the DDR on actual donors.

13. Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act (Organ Procurement Organization (OPO) Committee)

Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act, enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to concurrently amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).

14. Proposal to Allow Collective Patient and Wait Time Transfers (Operations and Safety Committee)

This proposal provides a process to transfer patients and their wait time collectively when a transplant program stops performing organ transplants due to a status change to one of the following:

- long-term inactivity
- withdrawal of membership
- termination of membership

Current policy and bylaws outline a process by which a registered individual can transfer primary waiting time. Processing large groups of patients who must transfer when a program stops performing transplants for an extended period is currently challenging. These situations could be handled safely and efficiently through a collective transfer process. This proposal outlines requirements to allow the OPTN to transfer patients collectively.

15. Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18 (Pediatric Transplantation Committee)

Under current liver policy, if a candidate turns 18 years old while waiting in a MELD score (i.e., not Status 1A, Status 1B, or inactive status), the candidate does not automatically retain pediatric classification. Rather the registering transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list, but returns to the waiting list as an adult, the registering transplant program has

the ability to apply to the RRB for a pediatric classification exception for this candidate. Both of these exception processes are inconsistent with allocation policy for other organs. The RRBs have been consistent in their decision-making on these applications, making review of these applications unnecessary and easily automated. The Pediatric Transplantation Committee proposes the automatic transfer of pediatric classification for all candidates who turn 18 while waiting for a liver transplant. Further, the Pediatric Transplantation Committee seeks to eliminate the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18 but has since been removed and reregistered.

16. Policy Rewrite Parking Lot "Quick Fixes" (Policy Oversight Committee)

In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and, the rewritten Policies became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the rewrite parking lot and offers the corrected policy language to further clarify the OPTN Policies.

17. Clarification of Multi-Organ Policies (Policy Oversight Committee)

Approximately 850 multi-organ transplants are performed each year. OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inaccurate. The organ–specific Committees are addressing multi-organ allocation issues, but the POC identified general multi-organ policies that could be clarified to support the organ-specific Committees' work, yet not interfere with the allocation issues and related language that they are addressing.

18. Proposal to Clarify Definition of Organ Transplant and Transplant Date (Policy Oversight Committee)

UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what should be reported as the transplant date, especially in regards to meeting reporting requirements in UNetSM. Members report that there is a disconnect in current definitions and actual clinical practices, and these proposed definitions will help bridge the disconnect and clarify the policy requirements.

II. Policy Proposals

- **Affected/Proposed Policies:** Policies 13.3 (Informed Consent for Candidates); 13.4 (Informed Consent for Potential Donors); 13.6.A (Requirements for Match Run Eligibility for Candidates); and 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors)

- **Kidney Transplantation Committee**

  The *Proposal for Informed Consent for Kidney Paired Donation* proposes required elements for informed consent for paired candidates and donors participating in any KPD program. The proposal requires transplant programs registering the paired candidates and donors to inform KPD participants of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process, including prioritization information and consequences of shipping kidneys. It also includes additional informed consent elements for non-directed donors (NDDs) and bridge donors participating in any KPD program. These informed consent requirements are intended to be supplemental and additional to the requirements required in Policy 14.3: Informed Consent Requirements.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Transplant Social Workers
  KPD Candidates
  Living Donors

- **Number of Potential Candidates Affected**
  This proposal will affect all candidates and donors participating in any KPD program. There are many other KPD programs across the United States, including the National Kidney Registry (NKR), the Alliance for Paired Donation (APD), and many regional and intra-hospital exchange programs. In the OPTN/UNOS KPDPP alone, as of June 26, 2014 approximately 250 eligible pairs participate in every KPD match run. Through June 30, 2014, NKR reported 1200 people in its cumulative paired patient pool and 350 currently active donors[1], while over 1,000 people have entered the KPDPP patient pool since its inception.[2] Candidates and donors may be registered in more than one KPD program.

- **Compliance with OPTN Strategic Plan and Final Rule**
  OPTN Strategic Plan Goal 4: Promote transplant patient safety
  OPTN Strategic Plan Goal 5: Promote living donor safety

[1] National Kidney Registry, "Paired Exchange Results Quarterly Results as of June 30th, 2014." Accessed on August 27, 2014. http://www.kidneyregistry.org/pages/p302/2_14.php

[2] "The State of the OPTN/UNOS KPD Pilot Program." Accessed on September 4, 2014. http://optn.transplant.hrsa.gov/ContentDocuments/KPD_Report.pdf

Proposal for Informed Consent for Kidney Paired Donation

Affected/Proposed Policy: Policies 13.3 (Informed Consent for Candidates); 13.4 (Informed Consent for Potential Donors); 13.6.A (Requirements for Match Run Eligibility for Candidates); and 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors)

Kidney Transplantation Committee

Public Comment Response Period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

The *Proposal for Informed Consent for Kidney Paired Donation* proposes required elements for informed consent for paired candidates and donors participating in any KPD program. The proposal requires transplant programs registering the paired candidates and donors to inform KPD participants of the risks and benefits of participating in the KPD program and the logistics of the KPD program's matching process, including prioritization information and consequences of shipping kidneys. It also includes additional informed consent elements for non-directed donors (NDDs) and bridge donors participating in any KPD program. These informed consent requirements are intended to be supplemental and additional to the requirements required in Policy 14.3: Informed Consent Requirements.

Background and Significance of the Proposal:

In March 2012, the Kidney Transplantation Committee (Kidney Committee) distributed for public comment the *Proposal to Establish Kidney Paired Donation (KPD) Policy*. The proposal included sections regarding informed consent, particularly sections 13.3 (Informed Consent for Candidates) and 13.4 (Informed Consent for Potential Donors).

Themes suggesting ways to improve the proposal before it became policy emerged from public comment, particularly regarding the informed consent sections of the proposal:

- "Modify Policy 13.4 so that it is clear who is responsible for informed consent from potential donors…" (Region 2)
- "…an element of informed consent is missing, namely understanding of the possibility that the donor could serve as a bridge donor, and the potential consequences thereof." (National Kidney Foundation).
- "…whenever possible all elements of the proposals (13.2, 13.3, 13.4) should mirror and should reference rather than duplicate requirements in [Living Donor policy]." (Living Donor Committee).

Joint Societies Work Group

After reviewing the public comment feedback submitted by the public at large, other OPTN/UNOS Committees and OPTN/UNOS regions, the Kidney Committee decided to remove the informed consent sections from the KPD policy proposal that was ultimately approved by the Board of Directors in November 2012. Additionally, the American Transplant Society (AST) and the American Society of Transplant Surgeons (ASTS) notified the KPD Work Group of their desire to discuss the informed consent sections of the proposed policy through a Joint Societies Policy Working Group (JSWG).

Based on the process established by the Rockville Policy Development Discussion, representatives from the Kidney Committee, AST, ASTS, and the North American Transplant

Coordinators Organization (NATCO) formed a JSWG in December 2012. The JSWG was charged to "provide recommendations to OPTN/UNOS regarding the development of informed consent policies for paired donors, candidates and non-directed donors entering the OPTN/UNOS KPD program. The KPD JSWG should provide recommendations regarding the risks and benefits of participating in the KPD program, the KPD matching process, and confidentiality and sharing of protected health information. The KPD informed consent policies are being developed in addition to existing informed consent policies that already apply to all candidates and living donors."

Using the policy language that was distributed for public comment in March 2012 as the starting point, the JSWG carried out its charge over a series of teleconferences spanning from January 2013 to October 2013. In October 2013, the JSWG finalized its recommendations and sent them to the Joint Societies Steering Committee for approval. The Joint Societies Steering Committee reviewed the JSWG recommendations, and ultimately approved them without modification in March 2014. The OPTN/UNOS KPD Work Group subsequently reviewed the JSWG proposal on April 25, 2014 and recommended that the Kidney Committee also approve it without modification.

The structure and content of the JSWG proposal was largely the same as the March 2012 proposal, with some notable modifications: 1) scope; 2) prioritization for candidates in a failed exchange; 3) bridge donor consent; 4) risks of shipping kidneys; and 5) provide donors with matched candidate's transplant hospital outcomes.

1. Scope

First, the JSWG recommended expanding the scope of informed consent policy to apply to all KPD programs. The JWSG held numerous discussions regarding the scope of KPD informed consent policies. OPTN/UNOS Policy 14: Living Donation applies to all living donors. The JSWG members considered of Policy 13: Kidney Paired Donation as a supplement to Policy 14, and therefore proposed that Policies 13.3 and 13.4 apply to all KPD programs.

The Kidney Committee agreed that the scope of KPD informed consent should be broadened to apply to transplant hospitals enrolling donors and candidates in any KPD program. The Kidney Committee clarified that these policies also apply to intra-hospital exchanges. As defined by OPTN/UNOS policy, an exchange is "a set of KPD matches that form a chain, a two-way exchange, or a three-way exchange." Furthermore, the only aspect of the proposed informed consent requirements that is not relevant to intra-hospital exchanges – shipping kidneys – is a minor piece of the entire informed consent process and would be difficult to remove for individual situations. Therefore, the Kidney Committee proposes that all of the KPD informed consent policies included in this proposal apply to transplant hospitals enrolling participants in <u>any</u> KPD program, including non-OPTN KPD programs and intra-hospital paired exchanges.

2. Prioritization for Candidates in Failed Exchange

The JSWG recommended each KPD program prioritize candidates in the event of a failed exchange, in which a paired donor donates but the paired candidate does not receive a kidney from their matched donor due to certain unforeseen circumstances. The JSWG acknowledged that prioritization differs by KPD program, but believed that a candidate in this circumstance should receive prioritization in the KPD program's matching system. Therefore, the JSWG used language that could broadly apply to all KPD programs, but did not specify a precise prioritization for the candidate in any program, only that the candidate be prioritized in some way.

The JSWG recommendation for remedying a candidate involved in a failed exchange included the requirement that the candidate be prioritized in the KPD program in which the exchange failed. The Kidney Committee believed this requirement to be too prescriptive, as it would have required all KPD programs to prioritize these candidates in some way. Instead, the Kidney Committee proposes requiring that transplant programs enrolling a candidate or donor in a KPD program advise the participant of that KPD program's remedy in the event of a failed exchange, or advise the participant that the KPD program does not have a remedy in the event of a failed exchange. If the transplant program is enrolling the paired donor or candidate in more than one KPD program, it must advise the donor and candidate of each KPD program's policies regarding prioritization of candidates subsequent to a failed exchange.

3. Bridge Donor Consent

The JSWG recommended removing the requirement that a bridge donor must verbally consent to continue as a bridge donor every three months, and instead suggested permitting the bridge donor to assert the amount of time he or she is willing to wait. The March 2012 proposal required bridge donors to consent on multiple occasions: before the transplant hospital reported that the donor was willing to be a bridge donor; every three months after the match run in which the donor has been identified as a bridge donor until the bridge donor donates, declines to be a bridge donor, or declines to donate; and upon identification of a matched recipient.

The JSWG considered three options for informed consent for bridge donors:

- Option 1:
  - No separate consent for a bridge donor at all (the donor already implicitly opted to be a bridge donor when he or she agreed to be a living donor)
- Option 2:
  - The transplant hospital obtains consent from the donor twice. The first consent is obtained when the donor initially agrees to be a bridge donor. The donor would be informed how the chain ends, and be provided an estimated amount of time for when the chain would be complete, so the bridge donor would not be "on call" for an indefinite amount of time. The second consent is obtained upon identification of a match.
- Option 3:
  - The transplant hospital obtains informed consent when the donor initially agrees to be a bridge donor, and subsequently at different intervals while the hospital is looking for a match for the bridge donor. The intervals would be different than the originally proposed three month intervals, and the chain could therefore remain open without giving the bridge donor an expected timeframe.

The JSWG engaged in many discussions regarding whether consent on multiple occasions is necessary for bridge donors. Some members believed that a donor's initial consent to be a bridge donor served as their consent. Others believed that obtaining informed consent on various occasions helped protect the donor's freedom to opt out of the donation process, and prevent the donor from being "on call" for an indefinite period of time. These members argued that verbal consent provided the donor the ability to opt out of donation in a non-pressured situation, and that failing to require the transplant hospital to continue to obtain consent could be coercive to the donor. The bridge donors should either have a limited timeframe in which to donate, or they should provide verbal consent at various time points, allowing them to opt out of the donation process.

Ultimately, the JSWG agreed to recommend Option 2, as it struck the appropriate balance between properly informing the donor without the risk of coercing the donor to continue to be a bridge donor longer than he or she truly feels comfortable.

In addition to the other informed consent elements for bridge donors, the JSWG proposal would have required a transplant hospital to obtain verbal consent from the bridge donor each time the donor was identified as a bridge donor in an "accepted match." The Kidney Committee determined that this requirement would be too burdensome, as "accepted matches" do not necessarily result in "accepted exchanges" that proceed to transplantation. The requirement would be difficult for transplant hospitals, and may also translate into donor consent fatigue. The Kidney Committee therefore recommends requiring the transplant hospital to obtain and document verbal consent from the bridge donor upon the event of an "accepted exchange." The Kidney Committee noted this requirement would be far less burdensome, as the bridge donor would already be required to begin the crossmatch process and would therefore be in touch with the transplant hospital.

4. Risks of Shipping Kidneys

The JSWG recommended advising both the paired donor and candidate of the inherent risks in shipping kidneys between transplant centers. The March 2012 proposal only required transplant hospitals to obtain written consent from the candidate to accept a shipped kidney. During discussion, some JSWG members felt this requirement was extraneous, noting such consent is implicit for recipients, as well as the lack of data on loss of living donor kidneys due to shipping. However, an OPTN/UNOS Committee member noted that there is a 1-2% loss of shipped deceased donor kidneys, and it is possible that loss of kidneys from living kidney donation will increase. In addition to obtaining written consent to accept a shipped kidney, the JSWG also recommended requiring the transplant hospital to inform the candidate about potential consequences of shipping a kidney. Therefore, the JSWG included in the proposal the requirement to inform the candidate of the potential for the donor kidney to be lost in transport, and that greater ischemic time could create a greater incidence of delayed graft function or need for dialysis.

The Kidney Committee agreed that both the candidate and the donor should be informed of the risks inherent to shipping kidneys and accepting shipped kidneys. However, the JSWG proposal contained a numbered list of potential consequences. The Kidney Committee determined the transplant hospitals should advise candidates about the risks of shipping or accepting shipped kidneys, but the list would not be prescribed in policy.

5. Provide Donors with Matched Candidate's Transplant Hospital Outcomes

The JSWG considered the following options regarding when to provide the KPD donor with information about the recipient hospital, and what information should be provided:

- Option 1
    - The recovery hospital informs the donor of the "national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports" including "national 1-year patient and graft survival."
    - When the recipient center becomes known, the recovery hospital must inform the donor of "the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports," including "the recipient hospital's 1-year patient and graft survival" and "notification about all CMS outcome requirements not being met by the recipient hospital."

- Option 2
    - The recovery hospital does not provide any information about outcomes *until* the matched recipient is identified.
    - Upon identification of the matched recipient, the recovery hospital informs the donor of the "national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports" including "national 1-year patient and graft survival," as well as the "recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR center-specific reports," including "the recipient hospital's 1-year patient and graft survival" and "notification about all CMS outcome requirements not being met by the recipient hospital."
- Option 3
    - The recovery hospital informs the donor of the "national program-specific transplant recipient outcomes from the most recent SRTR center-specific reports" including "national 1-year patient and graft survival."
    - Transplant hospitals that are not in good standing (either defined by bylaws or policy) are not permitted to participate in KPD.

The JSWG ultimately agreed upon Option 2. It noted that the donor should not bear the burden of asking for information on the matched recipient's hospital. Option 3 would have placed that onus on the potential donor. The JSWG noted that Option 2 aligns most closely with current CMS requirements, making the informed consent process more streamlined for the recovery hospital. Additionally, Option 2 permits the recovery hospital to complete the requirement in one step, rather than requiring the hospital to provide information to the potential donor at two separate times, as required by Option 1.

The JSWG recommendation filled a perceived "gap" in policy related to advising NDDs of the matched candidate's transplant hospital's outcomes "upon identification of the matched candidate" if the recovery hospital and the recipient hospital will not be the same and the recipient hospital is not known. Upon closer review, the Kidney Committee determined that this "gap" is actually already covered by in *Policy 14*: *Table 14-1: Required Recipient Outcome and Transplanted Kidney Survival Data*. If the recipient hospital and recovery hospital are not the same and the recipient hospital is not yet known, then it necessarily follows that the recovery hospital cannot provide the donor with the matched candidate's transplant hospital's outcomes. But, the recipient's transplant hospital will be known at some point, and at that moment "the recovery hospital and the recipient hospital will not be the same and the recipient hospital is known." Row two in Table 14-1 would then apply to this situation. Removing this requirement also adheres to the suggestion submitted by ASTS, which stated "Beyond adding another regulatory burden, it can threaten the anonymity of those involved. KPD is meant to expand the pool of organs available for transplantation and we encourage both the JSWG and OPTN [K]idney [C]ommittee to finalize recommendations aligned with the spirit of KPD and not create a regulatory burden that will hinder this growing area." The Kidney Committee therefore decided not to modify Table 14-1.

In addition to the informed consent elements included in this proposal, the Kidney Committee also proposed minor modifications to *Policy 13.6: Matching within the OPTN KPD Program*. These proposed modifications are specific to the OPTN KPD program, and do not apply to any other KPD program. The proposed modifications are intended to clarify policy and ensure that it reflects how the OPTN KPD system currently operates.

On August 4, 2014, the Kidney Committee voted unanimously to approve distributing this proposal for public comment (10 support; 0 oppose; 0 abstentions).

Supporting Evidence and/or Modeling:

A March 2012 Kidney Paired Donation Consensus Conference resulted in recommendations for informed consent for living kidney donors participating in paired donation.[3] The Consensus Conference recommendations are shown in **Figure 1**.

Consensus recommendations for KPD donor evaluation and care
1. All potential NDDs should be informed about KPD as an option prior to initiating evaluation
2. The medical and psychosocial evaluation of an NDD should be guided by the "Evaluation of the Living Kidney Donor – a Consensus Document from the AST/ASTS/ NATCO/UNOS Joint Societies Work Group" recommendations
3. NDDs should undergo preliminary (i.e. screening) assessment by a mental health professional before the medical evaluation is initiated
4. The National Living Donor's Assistance Center should provide travel and lodging expenses to the NDDs
5. In addition to the standard informed consent donor nephrectomy, KPD donor informed consent should include these additional elements: risks and benefits of non-KPD donation options, kidney transport, possible kidney redirection due to unforeseen circumstances, and the inability to provide information about the actual recipient
6. Donor privacy should be strictly protected. Specific consent should be obtained from the donor if their name is released to the press
7. The donor center evaluation processes and procedures at which the donor nephrectomy takes place should be followed
8. All evaluative studies (including anatomic imaging) should be completed before registering a donor in KPD and repeated after 12 months. Anatomical imaging, however, does not need to be routinely repeated

Figure 1: Consensus recommendations for KPD donor evaluation and care

Many of the recommendations are already incorporated into OPTN/UNOS policy, specifically *Policy 14.3: Informed Consent Requirements* (for living donation). As the JSWG, KPD Work Group and Kidney Committee view this proposal as a supplement to Policy 14, the only requirements included in the current proposal are those that directly relate to participation in paired donation. The proposed requirements are harmonious with recommendation #5 in Figure 1, as paired candidates and donors are to be advised of the risks of shipping kidneys, and the potential consequences of participating in paired donation, such as the risk of unforeseen circumstances that do not result in a kidney transplant. The proposal also requires transplant programs to advise candidates and donors of the KPD program's specific rules for when, or if, candidates and donors may meet.

[3] Melcher ML, Blosser CD, Baxter-Lowe LA, Delmonico FL, Gentry SE, Leishman R, Knoll GA, Leffell MS, Leichtman AB, Mast DA, Nickerson PW, Reed EF, Rees MA, Rodrigue JR, Segev DL, Serur D, Tullius SG, Zavala EY, Feng S. "Dynamic Challenges Inhibiting Optimal Adoption of Kidney Paired Donation: Findings of a Consensus Conference." *American Journal of Transplantation*, 13 (2013): 851–860. Accessed on August 29, 2014. doi: 10.1111/ajt.12140

Expected Impact on Living Donors or Living Donation:

This proposal will affect living donors participating in any KPD program as these proposed informed consent requirements will apply to all KPD programs. The impact on living donation should be positive, as the informed consent requirements will ensure that paired donors are fully informed of all risks, benefits and options of agreeing to be a living paired donor.

Expected Impact on Specific Patient Populations:

All KPD donors participating in the OPTN/UNOS KPD Pilot program as well as in any other KPD programs will be affected. In 2013, 350 donors were added to the OPTN KPD Pilot Program and 52 donated a kidney. Also in 2013, among the 5,732 living kidney donor transplants performed in the U.S., 587 were reported as having living donor relationship of "non-biological, unrelated: paired donation."[4]

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal adheres to the OPTN Key Goals to "Promote transplant patient safety" and even more specifically "Promote living donor safety" through Key Goals Objective A: Ensure that all living organ donors consent freely, through the stated strategy "Maintain effective standards for the consent of living donors" trough key initiatives such as adopting new policy for consent of potential living kidney donors, provide training/educational materials on new policies, and collaborate with other organizations to create and promote information for potential living kidney donors.

This proposal ensures that paired donors and candidates are advised of the risks and benefits related to participating in any paired donation program. Paired candidates and donors will be apprised of contingencies specifically related to paired donation, including potential adverse events, and will be protected from donating without risk of coercion. The proposal is a result of a collaboration between the OPTN/UNOS, NATCO, AST and ASTS. Lastly, the OPTN/UNOS will produce effective training and educational materials to advise transplant professionals and participants in KPD of these new informed consent policies.

Plan for Evaluating the Proposal:

Due to the nature of this proposal, there will not be an analytical evaluation.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and implemented on September 1, 2015. This proposal does not require programming in UNet^{SM}. All transplant hospitals participating in paired donation, either as a recovery hospital or a transplant hospital, must become familiar with the requirements in this

[4] Based on OPTN data as of August 15, 2014.

proposal. Upon implementation, transplant hospitals will be responsible for complying with the informed consent requirements in this proposal.

Communication and Education Plan:

This proposal will continue to be monitored for instructional needs. We may offer an instructional program in summer 2015 that will clarify for members updates to KPD policy and the KPD system. Any instructional methodology will allow a question and answer segment.

Communication & Education Activities

Upon board approval, we will communicate these changes to members and make educational materials available online.

- Policy notice on OPTN website
- OPTN news item(s)
- Article on Inside UNOS
- Presentation at Regional Meetings
- Formal training (if needed, summer of 2015)

Compliance Monitoring:
Members will be expected to consent patients based upon the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Members are required to provide documentation as requested.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

13.3 Informed Consent for KPD Candidates

~~*Reserved*~~

13.3.A Release of Protected Health Information

For any KPD exchange, a paired candidate will not be eligible for a KPD match run until the paired candidate's transplant hospital obtains written consent from the paired candidate to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired candidate's transplant hospital must maintain documentation of this consent in the paired candidate's medical record.

13.3.B Agreement to Accept a Shipped Kidney

The OPTN KPD program will only match a paired candidate with a donor whose recovery will occur at a transplant hospital that is different than the paired candidate's transplant hospital if the paired candidate's transplant hospital has obtained documentation in the candidate's medical record that the candidate is willing to receive a shipped kidney.

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that the candidate has been informed of the potentially negative

consequences related to shipping a kidney, including that the donor's kidney could be lost in transport.

13.3.C Additional Requirements for KPD Candidates

For any KPD exchange, the paired candidate's transplant hospital must document in the candidate's medical record that it has informed the paired candidate of all the following elements of the KPD program:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients
5. That even if the candidate's paired donor donates, the paired candidate might not be transplanted.
6. The KPD program's remedy for failed KPD exchanges

The paired candidate's transplant hospital must inform the candidate of the right to withdraw from participation in the KPD program at any time, for any reason.

13.4 Informed Consent for ~~Potential~~KPD Donors

~~*Reserved*~~

13.4.A Release of Protected Health Information (PHI)

For any KPD exchange, a paired donor will not be eligible for a KPD match run until the paired donor's transplant hospital obtains written consent from the paired donor to share protected health information (PHI) with all other transplant hospitals in the KPD exchange. The paired donor's transplant hospital must maintain documentation of this consent in the paired donor's medical record.

13.4.B General KPD Donor Informed Consent

For any KPD exchange, the paired donor's transplant hospital is responsible for obtaining and documenting informed consent from the paired donor according to *Policy 14: Informed Consent Requirements*. If a different transplant hospital performs the organ recovery, the recovery hospital must also obtain and document informed consent according to Policy 14.

13.4.C Additional Requirements for KPD Donors

For any KPD exchange, the paired donor's transplant hospital must maintain documentation in the paired donor's medical record that it has informed the paired donor of *all* of the following:

1. The KPD program's matching requirements
2. KPD donors and candidates do not choose their match
3. A KPD donor or a candidate may decline a match
4. The possibility of helping more than one candidate receive a transplant
5. The possibility that the paired donor may have to wait to find a match
6. The possibility that the paired donor might have to wait longer to donate after a match has been identified because of logistical issues

7. The possibility that the paired candidate might not receive a transplant because of an unexpected issue with the matched donor's kidney found during or after surgery
8. The possibility that the paired donor's kidney might not be transplanted or the paired donor's matched candidate might not receive a transplant because of unexpected events
9. The KPD program's remedy for failed KPD exchanges
10. The possibility that the matched candidate's insurance might not cover travel costs if the paired donor travels to the matched recipient transplant hospital
11. The possibility that the paired donor's paired recipient and the paired donor's matched recipient might not have equal outcomes
12. The possibility of the paired donor's name appearing on the matched candidate's insurance estimation of benefits
13. That the donor's kidney could be lost in transport, and other potentially negative consequences related to shipping a kidney.
14. That the paired donor may require additional testing, including multiple blood draws for crossmatching
15. The KPD program's rules for when members are allowed to facilitate meetings between matched donors and recipients

The paired donor's transplant hospital must inform the paired donor of the right to withdraw from participation in the KPD program at any time, for any reason.

13.4.D Additional Requirements for Non-Directed Donors (NDD)

For any KPD exchange, before a NDD can participate in the KPD program, the NDD's transplant hospital must document in the NDD's medical record that it has informed the NDD of all their donation options including:

1. Participating in KPD
2. Donating to a candidate waiting for a deceased donor kidney according to Policy 14.7.B: Placement of Non-directed Living Donor Kidneys
3. Any other options available in the NDD's donation service area

13.4.E Additional Requirements for Bridge Donors

For any KPD exchange, before a bridge donor is entered into a KPD match run, the bridge donor's transplant hospital is responsible for obtaining and maintaining documentation in the donor's medical record that it has informed the bridge donor of all the following:

1. The bridge donor may need to have another medical evaluation at a future time
2. The bridge donor may need to be available to provide blood on multiple occasions for crossmatching
3. How the KPD program determines whether a chain ends with a bridge donor
4. Approximately how long the bridge donor can expect to wait before undergoing surgery to recover the bridge donor's kidney, based on the experience of the bridge donor's transplant hospital. The bridge donor will have the option to revise the estimated amount of time the donor is willing be a bridge donor based on this information. The bridge donor's transplant hospital will document in the donor's medical record how long the donor is willing to be a bridge donor.

The bridge donor's transplant hospital must maintain documentation in the donor's medical record that the donor has verbally consented to remain a bridge donor each time the donor is identified as a bridge donor in an accepted KPD exchange.

13.6 Matching within the OPTN KPD Program

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with Policies *5.5.A: Receiving and Reviewing Organ Offers* and *5.5.D: Blood Type Verification upon Receipt*
2. The candidate's transplant hospital must complete the informed consent process according to ~~KPD Operational Guidelines~~*Policy 13.3: Informed Consent for KPD Candidates*
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:

a. Candidate details, including *all* of the following:
- Last name
- First name
- SSN
- Date of birth
- Gender
- Ethnicity
- ABO
- Whether the candidate has signed an agreement to participate in the OPTN KPD program
- Whether the candidate has signed a release of protected health information
- Whether the candidate is a prior living donor
- KPD status: active, inactive or removed. A candidate must have current active status in the OPTN KPD program to be eligible for a match run.

b. Candidate choices, including *all* of the following
- Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel or the distance the candidate is willing to travel
- Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
- Minimum and maximum acceptable donor age
- Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)
- Maximum acceptable donor BMI
- Maximum acceptable systolic and diastolic blood pressure
- Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
- Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney

~~4. The candidate must have current active status in the OPTN KPD program~~

4. ~~5.~~The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
5. ~~6.~~The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program, including reasons for refusing offers
6. ~~7.~~The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.4.A: Living Donor Blood type Determination* with the following modifications:

    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor
    b. Someone, other than the person who reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's actual blood type to the OPTN Contractor
    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to ~~KPD Operational Guidelines~~*Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the medical evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:

    a. Donor details, including *all* of the following:
        - Last name
        - First name
        - SSN
        - Date of birth
        - Gender
        - Ethnicity
        - ABO
        - Height and weight
        - Whether the potential KPD donor is a non-directed donor or a paired donor
        - If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
        - Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
        - Whether the potential KPD donor has signed a release of protected health information

- Whether the potential KPD donor has signed an informed consent as required in policy
- Whether the potential KPD donor has undergone a medical evaluation as required in *Policy 14.4: Medical Evaluation Requirements for Living Donors*.
- Whether the potential KPD donor has had all age appropriate cancer screenings as defined by the American Cancer Society
- KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

b. Clinical information, including *all* of the following:
- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
- Creatinine clearance or glomerular filtration rate (GF), date, and method
- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:
- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

~~5. The potential KPD donor must have current active status in the OPTN KPD program~~

5. ~~6.~~The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. ~~7.~~The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reasons for refusing offers
7. ~~8.~~The potential KPD donor must not be in a pending exchange in the OPTN KPD program

At-a-Glance

Proposal to Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy

- **Affected/Proposed Bylaws and Policy:** Bylaws Appendix E.5.F: Kidney Paired Donation (KPD) and Appendix E.5.G: Required Living Donor Protocols; and Polices 13.7.E: Prioritization Points, 13.7.F: OPTN KPD Waiting Time Reinstatement, 13.10: Crossmatching Protocol, 13.11: Transportation of Kidneys, and 13.12: communication between KPD Donors and Recipients.

- **Kidney Transplantation Committee**

  In June 2014, the OPTN/UNOS Board of Directors approved the removal of the "pilot" label from the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP). Though the "pilot" label will not be removed until the Board's decision is approved by the Health Resources and Services Administration (HRSA), the Kidney Committee believes it is appropriate to continue to transition sections of the operational guidelines into OPTN policy. Including these sections in OPTN policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN. Other sections of the operational guidelines were previously transitioned to OPTN policy in November 2012 and June 2014.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Social Workers
  KPD Candidates
  Living Donors
  KPD Contacts

- **Number of Potential Candidates Affected**
  This proposal will have a minimal but positive effect on all candidates and donors participating in the KPDPP, because it does not significantly change the way in which the KPDPP currently operates but will make the KPDPP more efficient.

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal meets the OPTN Key Goal to "increase the number of transplants" by "increasing the number of organ donors" and "facilitating matching of willing donor and recipient pairs among different transplant centers."

Proposal to Convert KPD Contact Responsibilities and Donor Pre-Select Requirements from the OPTN/UNOS Kidney Paired Donation Pilot Program Operational Guidelines into OPTN Policy

Affected/Proposed Bylaws and Policy: Bylaws Appendix E.5.F: Kidney Paired Donation (KPD) and Appendix E.5.G: Required Living Donor Protocols; and Polices 13.7.E: Prioritization Points, 13.7.F: OPTN KPD Waiting Time Reinstatement, 13.10: Crossmatching Protocol, 13.11: Transportation of Kidneys, and 13.12: communication between KPD Donors and Recipients.

Kidney Transplantation Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

In June 2014, the OPTN/UNOS Board of Directors approved the removal of the "pilot" label from the OPTN/UNOS Kidney Paired Donation Pilot Program (KPDPP). Though the "pilot" label will not be removed until the Board's decision is approved by the Health Resources and Services Administration (HRSA), the Kidney Committee believes it is appropriate to continue to transition sections of the operational guidelines into OPTN policy. Including these sections in OPTN policy is consistent with the principles of transparency and public participation that are hallmarks of the KPDPP and the OPTN. Other sections of the operational guidelines were previously transitioned to OPTN policy in November 2012 and June 2014.

These sections both aim to make the KPDPP's matching process more efficient, by ensuring that transplant hospitals respond to offers and perform exchange responsibilities in a timely fashion, and by requiring the pre-selection of donors for sensitized candidates in order to avoid futile match offers.

Background and Significance of the Proposal:

The Donor Pre-Select Requirements and the KPD Contact Responsibilities are both sections in the KPDPP Operational Guidelines.[1] Since November 2012, when the first operational guidelines were transitioned into policy, the KPDPP has been governed by both the operational guidelines and policy. The OPTN/UNOS Board of Directors, in June 2014, voted to remove the pilot label from the OPTN/UNOS KPD program to make the OPTN/UNOS KPD program permanent. As a permanent function of the OPTN/UNOS, the KPD program will ultimately be governed solely by OPTN/UNOS policies and bylaws.

Many sections of the operational guidelines have already transitioned to policy, including Prioritization Points (June 2014), Matching Within the OPTN KPD Program (November 2012), Transportation of Kidneys (November 2012) and Rules for When Donors and Recipients Can Meet (November 2012). Converting the guidelines to policy permits the OPTN to monitor compliance with the policies, and also commits the OPTN to transparency and public participation by submitting all future policy changes through the public comment process. As the guidelines become policy, the public will not only have input in how the KPDPP operates, but it will also be able to access the governing rules in one location.

[1] http://optn.transplant.hrsa.gov/resources/KPDPP.asp

The Kidney Committee proposes converting the Donor Pre-Select Requirements and KPD Contact Responsibilities to policy with minimal changes, so the overall impact of the transition will be small. However, transitioning the guidelines to policy will make the KPDPP even more transparent and easier to navigate.

Donor Pre-Select Requirements

In March 2012, a Consensus Conference convened "to address the dynamic challenges and complexities of KPD that inhibit optimal implementation."[2] KPD exchanges involve multiple candidates, multiple donors, and often require multiple transplant hospitals to cooperate in order to successfully recover kidneys and transplant all candidates in the exchange. Because "a match offer that falls through late in the process disrupts multiple potential transplants and incurs additional, potentially avoidable, costs," the Consensus Conference recommended that "recipient centers should preselect acceptable donors to increase the percentage of viable match offers."

The KPD Work Group quickly worked to implement a solution based on the Consensus Conference findings to reduce the number of turn-downs due to unacceptable antigens. In May 2012, the Work Group began developing a donor pre-select mechanism for the KPDPP. The tool would allow a transplant center to preview potential donors with whom their candidates might match. Entering a pre-acceptance allows the candidate to potentially match with that donor; however, the transplant center is not committing to accepting any future match offers. Entering a refusal prevents the candidate from matching with that donor in future match runs.

The KPD Work Group additionally established a calculated panel reactive antibody (CPRA) threshold at which candidates would only match with donors that had been pre-accepted. Based on data provided by UNOS staff, explained in more depth in the Supporting Evidence section below, the KPD Work Group determined that candidates with a CPRA of 90% or higher must use the donor pre-select tool to pre-accept or pre-refuse all donors with whom they may potentially match. The candidate will not match with any donor that is not pre-accepted. Transplant hospitals entering candidates in the KPDPP are encouraged to use this tool for candidates with any CPRA, but it is only mandatory for those candidates with a CPRA greater than or equal to 90%.

As explained in the June 2013 Kidney Committee Board Report[3], the KPD Work Group and Kidney Committee considered various options regarding the donor pre-select tool:

> The Workgroup recommended those donors who are a zero antigen mismatch be excluded from the 90% threshold requirement. This would add complexity to the programming requirements and significantly delay the donor pre-select tool from going live. Of the over 200 matches offered in the OPTN KPDPP thus far, only 1 offered has been a zero antigen mismatch. We could have this added, pending programming at a later date and continue to collect data on the number of zero mismatches offered.
>
> The group also recommended that the data be provided to transplant programs to explain why the pre-select tool is important.

[2] Melcher ML, Blosser CD, Baxter-Lowe LA, Delmonico FL, Gentry SE, Leishman R, Knoll GA, Leffell MS, Leichtman AB, Mast DA, Nickerson PW, Reed EF, Rees MA, Rodrigue JR, Segev DL, Serur D, Tullius SG, Zavala EY, Feng S. "Dynamic Challenges Inhibiting Optimal Adoption of Kidney Paired Donation: Findings of a Consensus Conference." *American Journal of Transplantation*, 13 (2013): 851–860. Accessed on August 29, 2014. doi: 10.1111/ajt.12140

[3] http://optn.transplant.hrsa.gov/CommitteeReports/board_main_KidneyTransplantationCommittee_6_26_2013_20_18.pdf (visited on August 14, 2014).

> Finally, the Workgroup recommended use of this tool for candidates listed with a lot of lower level unacceptable antigens.
>
> The KPD Workgroup considered not requiring the donor-preselect for any candidate or for candidates with a CPRA >=80%. However, given the data, the KPD Workgroup thought requiring candidates with a CPRA of >=90% had the most potential to significantly decrease the match decline rate.

In January 2013, the Kidney Committee voted to incorporate the Donor Pre-Select Requirements into the KPDPP Operational Guidelines. In June 2014, the KPD Work Group determined that the Donor Pre-Select Requirements should be transitioned to policy without any changes, and in August 2014, the Kidney Committee agreed.[4]

KPD Contact Responsibilities

The March 2012 Consensus Conference also provided helpful recommendations regarding the responsibilities of those people coordinating KPD exchanges, noting:

> The KPD process is highly complex, requiring extensive coordination between multiple coordinators, nurses and physicians at multiple programs. As a result, standardization of the content and timing of communication is paramount to maximize the confidence of all involved parties. Prompt responses to match offers should be required.

Previous versions of the Operational Guidelines delegated a number of responsibilities to the KPD Contact at each transplant hospital, but did not specify the timeframes in which the contact must act. The lack of deadlines created delays in the exchange process and kept potential donors and candidates out of subsequent KPD matching opportunities, as candidates and donors in pending exchanges are not eligible to appear in subsequent match runs. The KPD Work Group determined that it should establish firm deadlines with tangible consequences, namely, that the exchange will be terminated if the deadlines are not met. The KPD Work Group supported the concept of incorporating timelines, but stressed the importance of granting exceptions for extenuating circumstances.

The Work Group ultimately sent a proposal to the Kidney Committee in April 2014 to change the operational guidelines to include deadlines for certain actions between match offer and transplant. The proposal also included a section permitting extensions and outlining the process for requesting one. In order to streamline the extension process, the Work Group members determined that requests for extensions should be sent by the transplant program to the OPTN, which in turn will distribute the request to all others in the exchange. After review, the transplant programs involved in the exchange will submit their approval or denial of the extension to the OPTN, which will then notify the requesting transplant program of the decision.

[4] See *Policy 13.7.E: Donor Pre-Select*, below.

The Work Group sent the following proposed deadlines to the Kidney Committee for consideration:

Actor	Action	Deadline
Each transplant hospital that received a match offer	Enter preliminary response in the KPD system	2 business days of receiving offer
Matched donor's transplant hospital	Provide matched candidate's transplant hospital with the name and location of where the crossmatch kit is to be sent.	1 business day of receiving notification of exchange acceptance
Matched candidate's transplant hospital	Report results of the crossmatch to the OPTN contractor	13 days of receiving notification of the exchange acceptance
Matched donor's transplant hospital	Make all donor records accessible to the matched candidate's transplant hospital	2 days of receiving notification of exchange acceptance
Matched candidate's transplant hospital	Review the donor records and report a final acceptance/refusal to the OPTN Contractor	13 days of receiving notification of exchange acceptance

Figure 1: March 2014 KPD Work Group Proposal for Deadlines for KPD Contact Responsibilities for Operational Guidelines

The Kidney Committee reviewed the recommendations on April 7, 2014. The Committee modified the proposed deadlines to be "business days," with the exception of the deadlines for performing the crossmatch and reporting the results, and for reporting a final acceptance or refusal, which would both remain 13 days from notification of exchange acceptance. The Kidney Committee also clarified the language to ensure that the requirement to "make available" donor records does not mean the donor's hospital must ship the records. The Kidney Committee voted to adopt the proposed guidelines, effective September 1, 2014.[5]

As the KPDPP moved closer to permanence, the KPD Work Group evaluated which Operational Guidelines should be transitioned into policy. The KPD Work Group recognized the importance of putting the deadlines into policy, as they are crucial to ensuring the efficiency of the KPDPP's exchange process. The Work Group also suggested removing KPD contact responsibilities within operational guidelines that would be redundant with other policies, or that are no longer in practice.

The Kidney Committee again reviewed the KPD Work Group's recommendations on August 4, 2014. The Kidney Committee approved the Work Group's proposal, with a few minor modifications. It determined that "business days" should apply to every deadline for KPD contacts to achieve consistency. To the same end, the Kidney Committee agreed to change the deadline for the matched candidate's transplant hospital to provide the matched donor's hospital with the contents required for the crossmatch kit and the address at which to ship the blood samples from one day to two business days.

[5] Alcorn, James. "Changes to OPTN Bylaws and Policies from actions at June Board of Directors Meeting." Policy Notice. July 23, 2014. http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policy_Notice_07-24-2014.pdf. Accessed on August 28, 2014.

The Kidney Committee also added a step that was missing from the KPD Work Group's proposal. The new step creates a five business day deadline for the matched donor's transplant hospital to send the completed blood samples to the matched candidate's hospital. Without this step, the matched candidate's transplant hospital would have been held to a deadline that would be potentially impossible if it did not receive the blood sample from the matched donor's transplant hospital in ample time. The Kidney Committee determined that five business days is a reasonable deadline for this step and reflects common practice. The Kidney Committee debated whether to require overnight shipping for the blood sample. It ultimately decided not to include the requirement, as there may be extenuating circumstances in which the matched donor, or the matched donor's transplant hospital, could not ship the blood sample overnight. However, the Kidney Committee stressed that overnight shipping is very important, and transplant hospitals should ship overnight when possible. Additionally, the matched candidate's transplant hospital could specify in its crossmatch instructions to the matched donor hospital that the blood sample must be shipped overnight.

Lastly, the Kidney Committee retained the extension request process in the proposed policy to allow for flexibility in the exchange process. Transplant hospitals involved in an exchange have the option to allow an extension, or to refuse it so that all the candidates and donors involved in the exchange can be available for the next match run.[6]

On August 4, 2014, the Kidney Committee voted to send this proposal for public comment. (10 support, 0 oppose, 0 abstentions).

Supporting Evidence and/or Modeling:

The supporting evidence for the Donor Pre-Select was previously reported extensively in the Kidney Committee's June 2013 report to the Board of Directors[7]:

> Over 90% of match offers are declined [between October 27, 2010 and May 2, 2012]. 20% of matches have not reported a refusal reason. 40% might have accepted the match, but the exchange was terminated by another pair.
>
> Of the remaining 40% of refused matches:
> • 33% refused due to an actual or virtual positive crossmatch
> • 7% due to "candidate involved in a pending exchange" (with another program)
> • 60% due to various other donor or candidate reasons including: Donor unacceptable due to age, weight, size, medical history etc.
>
> When a match is declined, the remaining matches in that exchange are frequently terminated as well, increasing the overall decline rate.
>
> […]

[6] See *Policy 13.11: Receiving and Accepting KPD Match Offers*, below.

[7] http://optn.transplant.hrsa.gov/CommitteeReports/board_main_KidneyTransplantationCommittee_6_26_2013_20_18.pdf. Accessed on August 28, 2014.

> Although candidates are given a variety of choices to rule out donors prior to matching, donors frequently fall just outside the acceptable limit. For example, a candidate can set a maximum BMI of 35 and therefore match with a donor with a BMI of 34.9, in which the candidate may decline. In addition, a candidate may decline for a combination of donor characteristics, in which they would not decline on one characteristic independently. For example, a candidate may set a minimum CrCl of 80 and willing to accept a 65 year-old donor with a CrCl of 80, but the 32 year-old donor with a CrCl of 80 would be unacceptable and declined.
>
> […]
>
> The refusal reasons by candidate sensitivity level were analyzed… to see if a large percentage of refusals (due to virtual or actual positive crossmatch) were occurring for highly sensitized candidates.
>
> The crossmatch-related refusal rate showed an increasing trend by CPRA, from 3.8% for CPRA=0% to over 25% for CPRA>90%.
>
> In addition, as the number of "all other antibody specificities" increased, the crossmatch refusal rate also increased.
>
> When candidates with a CPRA of 90-100% and candidates with 10 or more antibody specificities are analyzed together, the crossmatch refusal rate was 81.8%.
>
> Given this information the KPD Workgroup supported a recommendation to require programs with candidates with a CPRA of 90% or higher to use the Donor Pre-select tool. These highly sensitized candidates would only match if a donor is pre-accepted; candidates with CPRA less than 90% would still be allowed to match with any donors that were not pre-refused (including those that were neither pre-accepted nor pre-refused). The Workgroup will start with 90% as the threshold required in the automated KPD solution and monitor outcomes.[8]

The KPD Work Group and Kidney Committee continue to monitor the impact of the donor pre-select tool and the CPRA threshold. Both groups are satisfied with its success thus far, and therefore recommend transitioning the Donor Pre-Select Requirement, as written in Operational Guidelines, into OPTN policy without modification.

The deadlines for KPD contact responsibilities were decided upon based primarily on anecdotal evidence. The members of the KPD Work Group and Kidney Committee have participated in numerous KPD exchanges, both within and outside the KPDPP, and determined that the deadlines proposed are reasonable based on common practice. Data were presented to the Work Group showing that 92% of match offers received responses within two days, supporting

[8] For the complete data report, see the Appendix.

the proposed preliminary match response deadline. As the deadlines did not become effective in KPDPP operational guidelines until September 1, 2014, the KPD Work Group has not yet monitored their effect.

Expected Impact on Living Donors or Living Donation:

This proposal will affect living donation with respect to those parties involved in the OPTN KPDPP. The proposed policies, currently in operational guidelines, make the KPDPP more efficient, so more matches are found and proceed to transplant in a timely manner.

Expected Impact on Specific Patient Populations:

No known impact to specific patient populations.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal meets the OPTN Key Goal to "increase the number of transplants" by "increasing the number of organ donors," and "facilitating matching of willing donor and recipient pairs among different transplant centers." The proposal helps facilitate the matching of willing donor and recipient pairs by making the process for doing so within the KPDPP more efficient.

Plan for Evaluating the Proposal:

The KPD Work Group will continue to monitor the efficacy of the donor pre-select tool, in particular by reviewing match success rates and refusal reasons for matched candidates with CPRA of 90% or higher.

In addition, the KPD Work Group will monitor the frequency of match offers being automatically declined due to exceeding the allowable response time of 2 business days. The KPD Work Group will also review the distribution of days between:

- the date of preliminary acceptance notification and the crossmatch date
- the date of preliminary acceptance notification and the date the crossmatch results are reported to the OPTN contractor
- the date of the preliminary acceptance notification and the date of final exchange acceptance or refusal
- the date of the match run and the date of transplant

Additional Data Collection:

No additional data collection is required with this proposal.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect September 1, 2015. Modifications to the KPD Operational Guidelines would be made at the same time.

Upon implementation, the Donor Pre-Select tool will continue to operate as it currently does. Transplant programs must therefore pre-accept any potential donors shown for candidates with a CPRA greater than or equal to 90 percent to potentially receive an offer from that donor. Any

donors that are not pre-accepted will be treated as pre-refused. Candidates do not receive offers from pre-refused donors. Pre-refusals and pre-acceptances may be entered for candidates with a lower CPRA; while doing so is not mandatory, it will make the match process more efficient.

Every transplant program participating in the KPDPP must appoint a KPD contact and alternate, and report their contact information to the OPTN contractor. The KPD contact must become familiar with all of the deadlines triggered by the receipt of a match offer or exchange acceptance so that exchanges in which their candidates or donors are participating do not terminate due to missed deadlines.

Communication and Education Plan:

This proposal will continue to be monitored for instructional needs. We may offer an instructional program in summer 2015 that will clarify for members updates to KPD policy and the KPD system. Any instructional methodology will allow a question and answer segment.

Upon board approval, we will communicate these changes to members and make educational materials available online.

- Policy notice on OPTN website
- OPTN news item(s)
- Presentation at Regional Meetings
- Formal training (if needed, summer of 2015)

Compliance Monitoring:

Members will be expected to accurately report data based upon the proposed language. However, the proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested.

Policy and Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

E.5 Kidney Transplant Programs that Perform Living Donor Recovery

A kidney recovery hospital is a designated kidney transplant program that performs the surgery to recover kidneys from living donors for transplantation. Kidney recovery hospitals must meet all the requirements of a designated kidney transplant program as outlined above and must also have:

1. Protocols and resources in place for performing living donor evaluations.
2. Surgical resources on site for open or laparoscopic living donor kidney recoveries.

Some pediatric living donor or kidney paired donation transplants may require that the living organ donation occurs at a hospital that is separate from the approved transplant hospital.

A. Potential Living Donor Medical Evaluation

The kidney recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor.

B. Psychological Assessments

The kidney recovery hospital must have the clinical resources to perform a psychosocial assessment of the potential donor's ability to make an informed decision. This psychosocial assessment should also confirm that the evaluation and donation are completely voluntary.

C. Independent Donor Advocate

The kidney recovery hospital must have an Independent Donor Advocate (IDA) who is not involved with the evaluation or treatment decisions of the potential recipient, and is a knowledgeable advocate for the potential living donor. The IDA must be independent of the decision to transplant the potential recipient and follow the Protocols that outline the duties and responsibilities of the IDA as described in *OPTN Policy 12.0*.

The goals of the IDA are:

- To promote the best interests of the potential living donor.
- To advocate the rights of the potential living donor.
- To assist the potential living donor in obtaining and understanding information about the consent process, evaluation process, surgical procedure, as well as the benefit of and need for follow-up care.

D. Primary Open Living Donor Kidney Surgeon

A Kidney donor surgeon who performs open living donor nephrectomies must be on site and must meet *one* of the following criteria:

- Completion of an accredited American Society of Transplant Surgeons (ASTS) fellowship with kidney certification.
- Completion of at least 10 open nephrectomies, including deceased donor nephrectomies or the removal of diseased kidneys, as primary surgeon or First Assistant. The open nephrectomies must be documented in a log that includes the date of recovery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

E. Primary Laparoscopic Living Donor Kidney Surgeon

A surgeon who performs laparoscopic living donor kidney recoveries must be on site and must have completed at least 15 laparoscopic nephrectomies in the last 5 years as primary surgeon or first assistant. Seven of these nephrectomies must have been performed as the primary surgeon, and this role should be documented by a letter from the fellowship program director. The laparoscopic nephrectomies must be documented in a log that includes the date of the surgery, the role of the surgeon in the procedure, the type of procedure (open or laparoscopic), and the medical record number or Donor ID.

F. Kidney Paired Donation (KPD)

~~Members~~Transplant hospitals that choose to participate in the OPTN KPD program must do *all* of the following:

1. Meet all the requirements of *Section E.5: Kidney Transplant Programs that Perform Living Donor Recovery* above.
2. Notify the OPTN Contractor in writing if the transplant hospital decides to participate in the OPTN KPD program. A transplant hospital must notify the OPTN Contractor in writing if it decides to quit its participation in the OPTN KPD program.
3. Provide to the OPTN Contractor a primary KPD contact that is available to facilitate the KPD match offer and transplant, and provide at least one alternate ~~kidney paired donation~~KPD contact that is a member of the hospital's staff and can fulfill the responsibilities required by policy.
4. ~~Members that choose to participate in any OPTN kidney paired donation program must agree to follow the kidney paired donation program rules (Operational Guidelines). Potential violations may be forwarded by the Kidney Transplantation Committee to the MPSC for review.~~

The requirements for the OPTN KPD Program are described in detail in *OPTN Policy 13*.

G. Required Living Donor Protocols

Kidney recovery hospitals must develop protocols that address:

1. The living donation process
2. Duties for the Independent Donor Advocate (IDA)
3. Medical evaluations
4. Informed consent

The requirements for these protocols are described in detail in *OPTN Policy ~~12~~14.0*.

13.7 KPD Screening Criteria

13.7.E Donor Pre-Select

If an OPTN KPD candidate has a CPRA greater than or equal to 90%, then the candidate's transplant hospital must use the Donor Pre-Select Tool to pre-accept or pre-refuse potential donors. The OPTN KPD candidate can only be matched with donors that are pre-accepted.

If an OPTN KPD candidate has a CPRA less than 90%, then the candidate's transplant hospital may use the Donor Pre-Select Tool to pre-accept or pre-refuse potential donors. The OPTN KPD candidate can be matched with all donors that are not pre-refused.

13.7.~~E~~F Prioritization Points

All OPTN KPD matches receive 100 base points. KPD matches will receive additional points according to *Table 13-2: OPTN KPD Prioritization Points* when the OPTN Contractor identifies all possible matches and exchanges from the list of eligible KPD donors and candidates. The OPTN Contractor will then prioritize the set of exchanges with the highest total point value.

Table 13-2: OPTN KPD Prioritization Points

If the:	Then the match will receive:
Candidate is a 0-ABDR mismatch with the potential donor	200 points
Candidate has a CPRA greater than or equal to 80%	125 points
Candidate is a prior living organ donor	150 points
Candidate was less than 18 years old at the time the candidate was registered in the OPTN KPD program	100 points
Candidate and potential donor are registered for the OPTN KPD program in the same region	25 points
Candidate and potential donor are registered for the OPTN KPD program in the same DSA	25 points
Transplant hospital that registered both the candidate and potential donor in the OPTN KPD program is the same	25 points
Potential donor has at least one of the other antibody specificities reported for the candidate	- 5 points

13.7.~~F~~G OPTN KPD Waiting Time Reinstatement

KPD waiting time begins on the day the candidate's transplant hospital registers the candidate in the OPTN KPD program. Candidates accrue 0.07 points per day from the date the candidate is registered ~~on~~ in the OPTN KPD program. A candidate will accrue KPD waiting time at both active and inactive status in the OPTN KPD program.

The OPTN Contractor will reinstate OPTN KPD waiting time to recipients, without interruption, if the OPTN KPD candidate experiences immediate and permanent non-function of any transplanted kidney and the KPD candidate is re-registered in the OPTN KPD program. Immediate and permanent non-function of a transplanted kidney is defined as *either*:

1. Kidney graft removal within the first 90 days of transplant documented by a report of the removal of the transplanted kidney.
2. Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min within 90 days of the kidney transplant.

KPD waiting time will be reinstated when the OPTN Contractor receives a request for reinstatement of KPD waiting time and the required supporting documentation from the KPD candidate's transplant hospital.

13.10 Crossmatching ~~Protocol~~ Requirements

The KPD candidate's transplant hospital must perform a preliminary crossmatch for candidates in the OPTN KPD program before the matched KPD donor's recovery procedure.

~~The transplant hospital registering the potential KPD donor is responsible for arranging shipment of the potential KPD donor's blood sample to the matched candidate's transplant hospital or the laboratory specified by the matched candidate's transplant hospital.~~

The KPD candidate's transplant hospital is responsible for performing the crossmatch and reporting the results to the OPTN Contractor and the matched KPD donor's transplant hospital.

13.11 Receiving and Accepting KPD Match Offers

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

Table 13-2: Timelines for Performing Responsibilities upon Receiving a KPD Match Offer

Upon receipt of a match offer in the OPTN KPD program, the following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report a preliminary response to the OPTN Contractor	2 business days of receiving the match offer.
The matched candidate transplant hospital	Provide the matched donor's transplant hospital with contents required in the crossmatch kit, instructions for the donor and the address at which to send the completed blood samples.	2 business days of receiving notification of preliminary offer acceptance.
The matched donor transplant hospital	Send the completed blood samples to the address specified by the matched candidate's hospital.	5 business days of receiving the information about the contents required for the crossmatch kit and instructions for the donor and the address at which to send the completed blood samples.
The matched donor transplant hospital	Make all of the matched donor's records accessible to the matched candidate's transplant hospital. The matched donor's records must include any updated serology and NAT testing results, and must indicate whether the matched donor is increased risk according to the PHS Guidelines.	2 business days of receiving notification of preliminary exchange acceptance.
The matched candidate transplant hospital	Report the results of the crossmatch to the OPTN Contractor	13 business days of receiving notification of preliminary exchange acceptance.

Upon receipt of a match offer in the OPTN KPD program, the following members:	Must:	Within:
The matched candidate transplant hospital	Review the matched donor's records and report a final acceptance or refusal of the match to the OPTN Contractor	13 business days of notification of preliminary exchange acceptance.

If the matched candidate and matched donor transplant hospitals do not meet the deadlines specified above, then the exchange will be terminated, unless all transplant hospitals in the exchange agree, before the deadline expires, to extend the deadline. The transplant hospital requesting the extension must submit the request in writing to the OPTN Contractor explaining the reason for the request and include the new requested deadline date.

Upon receipt of the request for extension, the OPTN Contractor will notify all of the transplant hospitals in the exchange. The transplant hospitals in the exchange will have 1 business day to respond to the request for extension. If all other transplant hospitals in the exchange agree to the extension, it will be granted and the exchange will not be terminated. If any of the transplant hospitals in the exchange fail to respond to the request for extension within 1 business day of receiving the request, the request will not be granted. If the extension request is submitted before the deadlines specified in Policy 13.10, the exchange will not terminate until the resolution of the extension request or until the deadline is reached, whichever comes first.

13.11~~1~~2 Transportation of Kidneys

For any KPD exchange, the recovery hospital is responsible for packaging, labeling, and transporting kidneys from donors according to *Policy 16.2: Organs Recovered by Living Donor Recovery Hospitals*.

In the OPTN KPD program, the recovery hospital must specify *both* of the following:

1. The location where the recovered kidney must be picked up for transport to the recipient's transplant hospital.
2. The name and telephone number of the person or company who will package and label the kidney.

The recipient's transplant hospital must document *both* of the following:

1. The location where the recovered kidney must be delivered.
2. The name and telephone number of the person or company who will be transporting the kidney from the time that the kidney is recovered until the kidney is delivered to the location specified by the KPD recipient's transplant hospital.

The recovery and recipient hospitals must complete this documentation, along with the date and time it was documented, before the potential KPD donor enters the operating room for the kidney recovery surgery and must maintain this documentation in the donor's medical record.

13.12~~2~~3 Communication between KPD Donors and Recipients

The following rules apply to communication between KPD donors and matched KPD recipients that participated in an OPTN KPD program exchange. These rules do not apply to meetings between potential KPD donors and paired KPD candidates.

Members can facilitate communication such as meetings or other correspondence between KPD donors and their matched recipients that participated in an OPTN KPD program exchange only if *all* of the following conditions are met:

1. All the KPD donors and recipients participating in the communication agree on the conditions of the meeting or correspondence.
2. The meeting or correspondence occurs after the donor kidney recovery and transplant surgeries have been completed.
3. The transplant hospital establishes and complies with a written protocol for when KPD donors and their matched recipients can communicate. This protocol must include, at a minimum, the timing of the meeting or correspondence and what staff must be involved.
4. The ~~T~~transplant hospital complies with the written protocol for when KPD donors and recipients can communicate. The transplant hospital must maintain documentation of compliance in the KPD donor's or matched recipient's medical record.

FINAL REPORT

OPTN Kidney Paired Donation Work Group *Descriptive Data Request*

OPTN KPD MATCH OFFER OUTCOMES AND REFUSAL REASONS, BY CANDIDATE CPRA

FOR KPD MATCH RUNS: OCT 27, 2010 – MAY 2, 2012

Prepared for:
Kidney Paired Donation Work Group
Teleconference Meeting
July 13, 2012

By:
Darren Stewart
Catherine Monstello
UNOS Research Department

Table of Contents

BACKGROUND/PURPOSE

As of May 2, 2012, 19 transplants have been facilitated through the OPTN KPD Pilot Program (KPDPP). A large percentage of the candidates that have been entered into the national system are considered "difficult to match" – either blood group O, highly sensitized (e.g., CPRA>=80%), or both. Nonetheless, matches have frequently been found for high CPRA candidates in the OPTN KPDPP. However, many of these matches have not led to transplant, for a variety of reasons: patients involved in a pending match in another KPD program; patients refusing the donor due to donor characteristics; and refusals due to positive crossmatches or unacceptable donor antigens.

Due to the apparent high rate of exchanges falling apart due to unexpected positive crossmatches and/or unacceptable donor antigens, the KPD work group is interested in having KPD programs pre-accept or pre-refuse donors that may potentially match with their candidates in a future KPD match run. The work group has discussed the idea of making donor pre-screening mandatory for certain candidates based on CPRA, since higher CPRA candidates are generally associated with higher refusal and positive crossmatch rates.

To better understand the relationship between KPD match refusal rates/reasons and candidate CPRA, as well as to possible help establish a CPRA threshold for requiring donor pre-screening, the KPD work group has requested an analysis of KPD match refusal rates and reasons by candidate CPRA.

WORK PLAN ITEM ADDRESSED

Implement a kidney paired donation pilot program and begin to match pairs of donors and recipients in 2010. Develop and issue for public comment proposed interim policies for kidney paired donation.

COMMITTEE REQUEST

Tabulate the number of refusals, refusal rates, and refusal reasons by candidate CPRA for all KPD match runs for which enough time has lapsed to collect match response (accept/refuse) data.

DATA AND METHODS

This analysis is based on the data collected to operate the OPTN KPDPP since the inception of the program through June 13, 2012. Outcomes of match offers for match runs #1-20 (Oct 27, 2010 – May 2, 2012) are included. Match runs after May 2, 2012 could not be included since match offer response data was still in the process of being collected when this analysis was performed.

CPRA is based on the unacceptable antigens provided by the center for the purpose of screening off unwanted KPD match offers. The CPRA is based on the unacceptable antigens for each candidate as of the time candidate eligibility is determined prior to each KPD match run. In addition

to unacceptable antigens, centers can also list "other antibody specificities," which represent donor antigens that alone would not rule out transplantation, but in combination may result in a positive crossmatch. These "undesirable" antigens do not preclude the KPD system from matching candidates with donors; however, the optimization algorithm downweights such matches to decrease the likelihood of selecting them for inclusion in a potential KPD exchange.

After each match run, match offer(s) were sent to each transplant center having KPD candidate(s) involved in a 2-way or 3-way exchange, or non-directed donor (NDD) chain, as determined by the KPD optimization algorithm. Centers have the opportunity to initially refuse the offer or preliminarily accept it. If they preliminarily accept, they may later refuse after a crossmatch has been performed. Even if the center submits both a preliminary and final acceptance of match offer and schedules an OR date, it is still possible that such a match offer could end up not resulting in a transplant due to unforeseen circumstances. For both the preliminary and the final refusal, centers have the opportunity to provide both a primary and secondary reason; typically, however, only a primary reason is provided. Centers can select a one of the available refusal codes (e.g., "Matched donor: Weight") or write-in a custom reason by selecting "Other, specify."

Each of the 218 KPD match offers was classified as into one of the following four categories, based on the outcome of the offer:

(1) transplant,
(2) transplant pending,
(3) "exchange fell through," or
(4) match refusal.

The "match success rate" is simply the number of matches that resulted in a transplant divided by the total number of matches.

Matches in which the "exchange fell through" are cases in which a center may have been willing to accept a donor on behalf of their KPD candidate but was unable to accept because other matches in the exchange were refused, preventing the entire exchange from proceeding to transplant. Any match offer that a center refused for a reason other than "exchange fell through" (including those identified from the "Other, specify" text) was considered a "match refusal."

Crossmatch-related refusals are a subset of the match refusals. They include any match for which either the preliminary or final response (either primary or secondary reason) included one (or more) of the following four refusal codes:

- 2001 - Donor: Crossmatch unacceptable
- 2080 – Matched Donor: Candidate antibodies against donor antigens are unacceptable
- 2302 – High CPRA
- 2306 – Positive Crossmatch

In addition, refusals were considered crossmatch-related if the "Other, specify" text contained verbiage clearly consistent with crossmatch or unacceptable antigens; for example, "recipient had DSA's" was considered crossmatch-related.

The crossmatch-related refusal rate is the number of crossmatch-related refusals divided by the total number of match offers.

For nearly 15% of match offers, the transplant center did not provide a reason for refusal. It is possible that some of these refusals were related to a positive crossmatch or unacceptable antigens.

Table 4 shows the frequency of all refusal reasons provided by users. Matches with multiple refusal reasons among preliminary/final and primary/secondary fields were included once for each distinct reason; hence, the total number of refusal reasons (238) in Table 4 exceeds the number of match offers (218) shown in Tables 1-3. The "Other, specified" text responses have been redacted to remove individual and institutional identifiers, as applicable.

A small number, 9, of the KPD matches were the result of "repairing" a NDD-chain. In these cases, the exchange fell apart due to one or more match refusal(s) early in the chain. With KPD Work Group approval, UNOS staff was able to "repair" the chain by find a compatible candidate further down in the chain that matched with a refused donor earlier in the chain. These repairs are likely to have a higher success rate, since they are screened ahead of time during communication with the transplant centers prior to actually making the offers. (Note: Per KPD Work Group guidance, UNOS staff is no longer repairing broken chains.)

This analysis excluded match offers to the final candidate in an NDD chain; these are candidates on the deceased donor waitlist and not necessarily in the KPD system.

Sample sizes are small, so apparent differences in rates may be exclusively or predominantly due to random variability and thus should be interpreted cautiously. However, statistical analyses were conducted to test the hypotheses that there is no relationship between the crossmatch-related refusal rate and CPRA. Logistic regression was used for these analyses, with CPRA a continuous independent variable, as well as a categorical variable; in both cases, p-values (based on the likelihood ratio test) were similar. A similar logistic regression analysis was also conducted for the association between the crossmatch-related refusal rate and the number of other antibody specificities. The 95% confidence interval cited in the results is derived using the Wilson/Score-based methodology for binomial proportions.

RESULTS

Table 1 shows that the overall match success rate – the number of match offers that resulted in a transplant divided by the total number of match offers – was 7.4%. Though there is no discernible trend in the match success rate with respect to CPRA, this is likely an artifact of a small sample size (N=16 transplants). It is possible that a relationship between CPRA and the match success rate exists, but with only 1-3 transplants in many of the CPRA groups, much of variation seen in the match success rates (for example, the 20% rate for the CPRA of 80-89 group) is likely due to random variability and not a real phenomenon.

However, the rate of offers being refused due to a crossmatch-related issue does appear to be a function of candidates' CPRA. Though the overall rate of refusing for crossmatch-related reasons was 14.7%, the rate was 34.8% and 25.8% for candidates in the CPRA 90-95 and 96-100 groups, respectively. In spite of the limited sample sizes, the relationship between CPRA and the crossmatch-refusal rate is statistically significant ($p<0.01$).

Based on the relationship between the crossmatch-related refusal rate and CPRA in Table 1, for subsequent analyses CPRA was broken into the following three groups: 0, 1-89 and 90-100.

Table 2 shows a higher crossmatch-related refusal rate for candidates with a large number of "other antibody specificities." For those with 10 or more undesirable antigens listed in the OPTN KPD system, the crossmatch-related refusal rate was 52.4%. The relationship between the number of other antibody specificities and the crossmatch-refusal rate is also statistically significant ($p<0.01$).

For candidates with CPRA of 90-100 and with 10 or more other antibody specificities, the estimated refusal rate due to crossmatch-related reasons jumped to 81.8% (**Table 3**). Though this rate is based on a fairly small sample size (9 refusals out of 11 match offers), a 95% confidence interval for the true rate is (52.3%, 94.9%) suggests that the true crossmatch-related refusal rate for these candidates, at a minimum, exceeds 50%.

Table 4 shows all reported refusal reasons provided during the first 20 OPTN KPDPP match runs, including "Other, specify" reasons provided in free form text by users. The most prevalent reason was actually not a refusal reason at all: the center intended to accept, but was unable to because another match in the exchange was refused and thus the entire exchange fell through. Table 4 also shows that cross-match related reasons are disproportionately represented among the match offers to candidates with CPRA of 90-100.

Table 1: OPTN KPD System Match Offers, Transplants, and Refusals by Candidate CPRA

	Match Offers	Transplants	Pending Transplants	Match Success Rate	Exchange Fell Through	Match Refusals	Crossmatch-related Refusals	Crossmatch-related Refusal Rate
CPRA								
0	79	9	1	11.5%	41	28	3	3.8%
1-49	32	1	0	3.1%	12	19	6	18.8%
50-79	38	1	0	2.6%	19	18	5	13.2%
80-89	15	3	0	20.0%	5	7	2	13.3%
90-95	23	1	0	4.3%	6	16	8	34.8%
96-100	31	1	0	3.2%	13	17	8	25.8%
All	218	16	1	7.4%	96	105	32	14.7%

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded

Table 2: OPTN KPD System Match Offers, Transplants, and Refusals by Candidate # Other Antibody Specificities
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	Match Offers	Transplants	Pending Transplants	Match Success Rate	Exchange Fell Through	Match Refusals	Crossmatch-related Refusals	Crossmatch-related Refusal Rate
# Other Antibody Specificities								
0	178	13	1	7.3%	79	85	18	10.1%
1-9	19	3	0	15.8%	12	4	3	15.8%
10+	21	0	0	0.0%	5	16	11	52.4%
All	218	16	1	7.4%	96	105	32	14.7%

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Match Success Rate = (# Transplants / # Match Offers)
Exchange Fell Through: Match May Have Been Accepted but Had to be Refused due to Other Match(es) Falling Apart
Crossmatch-Related Refusal: Refused due to Positive Crossmatch, Unacceptable Antigens, or DSA's
Based on OPTN KPD data as of June 13, 2012

Table 3: OPTN KPD System Match Offers, Transplants, and Refusals by Candidate CPRA & Other Antibody Specificities
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

		Match Offers	Transplants	Pending Transplants	Match Success Rate	Exchange Fell Through	Match Refusals	Crossmatch-related Refusals	Crossmatch-related Refusal Rate
CPRA	**# Other Antibody Specificities**								
0	**0-9**	75	9	1	12.2%	38	27	3	4.0%
	10+	4	0	0	0.0%	3	1	0	0.0%
1-89	**0-9**	79	5	0	6.3%	34	40	11	13.9%
	10+	6	0	0	0.0%	2	4	2	33.3%
90-100	**0-9**	43	2	0	4.7%	19	22	7	16.3%
	10+	11	0	0	0.0%	0	11	9	81.8%
All		218	16	1	7.4%	96	105	32	14.7%

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Match Success Rate = (# Transplants / # Match Offers)
Exchange Fell Through: Match May Have Been Accepted but Had to be Refused due to Other Match(es) Falling Apart
Crossmatch-Related Refusal: Refused due to Positive Crossmatch, Unacceptable Antigens, or DSA's
Based on OPTN KPD data as of June 13, 2012

Table 4: OPTN KPD System Match Offer Refusal Reasons by Candidate CPRA
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	CPRA						All	
	0		1-89		90-100			
	N	%	N	%	N	%	N	%
Refusal Reasons								
2081: Accepted but exchange fell through	31	37.3	26	28.0	14	22.6	71	29.8
Not reported	17	20.5	12	12.9	6	9.7	35	14.7
2082: Matched donor not considered because exchange fell through	10	12.0	7	7.5	4	6.5	21	8.8
2311: Other specify	5	6.0	11	11.8	3	4.8	19	8.0
2080: Matched Donor: Candidate antibodies against donor antigens are unacceptable	2	2.4	7	7.5	9	14.5	18	7.6
2001: Donor: Crossmatch unacceptable	1	1.2	6	6.5	6	9.7	13	5.5
2083: Candidate involved in a pending exchange	0	0	7	7.5	1	1.6	8	3.4
2604: Candidate ill, unavailable, or temporarily unsuitable	3	3.6	2	2.2	2	3.2	7	2.9
2002: Matched Donor: Number of HLA mismatches unacceptable	1	1.2	0	0	3	4.8	4	1.7
2023: Candidate already received transplant	1	1.2	1	1.1	2	3.2	4	1.7
2606: Matched Donor refused candidate	1	1.2	1	1.1	1	1.6	3	1.3
2603: Candidate refused	0	0	1	1.1	1	1.6	2	0.8
2012: Donor: Other specify	1	1.2	0	0	1	1.6	2	0.8
2006: Matched Donor: Weight	1	1.2	0	0	1	1.6	2	0.8
2607: Matched Donor ill, unavailable, or temporarily unsuitable	1	1.2	1	1.1	0	0	2	0.8
2404: Intended donor ill, unavailable, or temporarily unsuitable	1	1.2	1	1.1	0	0	2	0.8
2307: Candidate cannot be contacted	0	0	0	0	1	1.6	1	0.4
reason for match refusal is chain fell through	0	0	1	1.1	0	0	1	0.4
The reason for not accepting is positive crossmatch for another recipient in this swap.	0	0	1	1.1	0	0	1	0.4
BP	0	0	0	0	1	1.6	1	0.4
One of the other candidate s centers declined to accept the donor due to BMI.	0	0	0	0	1	1.6	1	0.4
Donor was declined by other center.	0	0	1	1.1	0	0	1	0.4
2004: Matched Donor: Distance for donor kidney to be shipped too far for candidate	0	0	0	0	1	1.6	1	0.4
New antibody that is unacceptable to this donor was discovered since entering.	0	0	0	0	1	1.6	1	0.4
Never crossmatched but after diluting recipient serum, revealed more DSA than previously thought.	0	0	1	1.1	0	0	1	0.4

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Matches with Multiple Refusal Reasons (Preliminary, Final/Primary, Secondary) Included Once for Each Distinct Reason
Free-form Refusal Reasons ('Other: Specify') Redacted to Omit Individual and/or Institutional Identifiers
Based on OPTN KPD data as of June 13, 2012

Table 4: OPTN KPD System Match Offer Refusal Reasons by Candidate CPRA
Includes the 20 Match Runs from Oct 27, 2010 through May 2, 2012

	CPRA						All	
	0		1-89		90-100			
	N	%	N	%	N	%	N	%
The recipient had DSA's	0	0	0	0	1	1.6	1	0.4
2019: Kidney: Organ anatomical damage or defect	0	0	1	1.1	0	0	1	0.4
candidates donor was requested tohave an open nephrectomy and refused	0	0	1	1.1	0	0	1	0.4
2608: Donor cannot be contacted	1	1.2	0	0	0	0	1	0.4
2007: Matched Donor: ABO	0	0	0	0	1	1.6	1	0.4
2022: Insurance Issues	0	0	0	0	1	1.6	1	0.4
2005: Matched Donor: Age	0	0	1	1.1	0	0	1	0.4
2009: Matched Donor: Medical history	1	1.2	0	0	0	0	1	0.4
matched donor at XXXX-TX1 already invovled in another exchange.	1	1.2	0	0	0	0	1	0.4
candidate receiving a transplant from a compatible daughter	1	1.2	0	0	0	0	1	0.4
3 renal arteries	0	0	1	1.1	0	0	1	0.4
size mismatch	1	1.2	0	0	0	0	1	0.4
2018: Kidney: Size	1	1.2	0	0	0	0	1	0.4
paired donor inactive	0	0	1	1.1	0	0	1	0.4
candidate found another living donor	0	0	1	1.1	0	0	1	0.4
kidney abnormality	1	1.2	0	0	0	0	1	0.4
All	83	100.0	93	100.0	62	100.0	238	100.0

Repaired Matches were Included, but Waitlist Candidates at the End of Chains were Excluded
Matches with Multiple Refusal Reasons (Preliminary, Final/Primary, Secondary) Included Once for Each Distinct Reason
Free-form Refusal Reasons ('Other: Specify') Redacted to Omit Individual and/or Institutional Identifiers
Based on OPTN KPD data as of June 13, 2012

At-a-Glance

Proposal for the Definition of Pancreas Graft Failure

- **Affected/Proposed Policy:** Policy 1.2 Definitions, Policy 3.6.B.ii Non-function of a Transplanted Pancreas,Tiedi Help Documentation, Pancreas and Kidney-Pancreas OPTN Data Collection Forms

- **Pancreas Transplantation Committee**

  Currently, there is no nationally and consistently utilized definition specifically for how to identify and document pancreas allograft failure. Pancreas transplant programs reporting when a pancreas graft failed varies due to no standard definition, and thereby, limits the ability to analyze and compare pancreas programs' outcomes.

  The proposal's purpose is to draft policy that assists transplant professionals to identify when pancreas allograft failure occurs and how to document the pancreas graft failure event. The proposal achieves this purpose by drafting policy for when a pancreas graft failed, updating Tiedi help documentation surrounding how to document pancreas graft failure, and updating the graft status section in the pediatric and adult pancreas and kidney-pancreas OPTN Recipient Registration and Recipient Follow-Up forms. (Unless otherwise noted, "OPTN pancreas forms" refers to the adult and pediatric pancreas and kidney-pancreas Transplant Recipient Registration Form (TRR) and Transplant Recipient Follow-up Form (TRF) throughout the proposal.)

  The Pancreas Transplantation Committee (the Committee) understands the essential and urgent need to measure, and thereby manage outcomes. Although the proposed changes are a significant step forward in the effort for transplant professionals to consistently identify and document pancreas graft failure on a national basis, the Pancreas Transplantation Committee acknowledges the proposed language has room for growth. Currently, the OPTN policy requirements for reporting pancreas graft failure do not consistently coincide with all current, clinical definitions of pancreas graft failure. Nor does OPTN policy identify all potential scenarios for when pancreas graft failure may occur. As such, the Committee decided to respond to the imminent need with this proposal and believes this proposal is a significant first step in achieving consistent identification and documentation of pancreas graft failure throughout the U.S. In turn, creating a foundation for which transplant programs may be monitored.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients

- **Number of Potential Candidates Affected**
  The number of potential transplant recipients affected includes all patients who have or will have received a pancreas transplant. As of September 2, 2014 there are 1,175 pancreas candidates and 2,048 kidney-pancreas candidates on the waiting list. Over the last five years there have been an average of 302 pancreas transplants and 867 kidney-pancreas transplants per year. After implementation of this policy proposal all pancreas recipients will be a part of the affected population and all pancreas recipients who have already received a pancreas transplant and the pancreas graft has not been reported, on OPTN pancreas forms as a failure, will be an affected population as well.

- **Compliance with OPTN Strategic Goals and Final Rule**
  Pancreas transplant programs' graft outcomes cannot be accurately and fairly analyzed and compared to a national standard since varying definitions of pancreas graft failure is used throughout the network. A consistent definition will allow for uniformly reported allograft failure, which will allow for improved estimates of expected graft failure using national data. This change will promote transplant patient safety, members' abilities to self-assess their performance, and members' abilities to strive for improvements.

- **Specific Requests for Comment**
  We welcome comments on the entire proposal. In addition, the Committee seeks feedback on the following specific additional questions:

  - Please provide any recommended changes to the general definition of graft failure. Should there be one general definition for graft failure? Alternatively, should there be organ specific definitions of graft failure?
  - Do you support including recipient deathsin the definition of pancreas graft failure? Should all recipient deaths count as graft failure?
  - Should programming the proposed additional fields on the OPTN pancreas forms be implemented simultaneously as the proposed policy language? If programming the additional fields will take approximately three years, should the proposed policy language be implemented in three years?

Proposal for the Definition of Pancreas Graft Failure

Affected/Proposed Policy: Policy 1.2 Definitions, Policy 3.6.B.ii Non-function of a Transplanted Pancreas, Tiedi Help Documentation, Pancreas and Kidney-Pancreas OPTN Data Collection Forms

Pancreas Transplantation Committee

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

The proposal's purpose is to draft policy that help transplant professionals identify when pancreas allograft failure has occurred and how to document the pancreas graft failure event. The proposal achieves this purpose by drafting policy for when a pancreas graft failed, updating Tiedi help documentation surrounding how to document pancreas graft failure, and updating the graft status section in the OPTN pancreas forms.

Background and Significance of the Proposal:

There has been concern that transplant centers report graft failures at different clinical endpoints. For example, some programs report a graft as failed if there is any return to insulin therapy whereas other programs only report failure if insulin use rises above a certain threshold. Dosage of insulin, duration of insulin therapy, c-peptide levels, and Hba1c are some parameters that can vary widely in patients who have been determined to have graft failure at their respective institutions. As the MPSC implements use of statistical models to assess pancreas program performance, this difference in reporting could impact whether a pancreas program is identified for outcome review under *Appendix D.10 A. Transplant Program Survival Rates*. Therefore, the Committee drafted a definition for pancreas allograft failure in order to set a measurable standard for what constitutes pancreas graft failure.

As background, the Tiedi help documentation includes guidance on how to categorize a functioning, partial functioning, and failed pancreas graft. In pertinent part, the current Tiedi help documentation reads:

- **Functioning:** The graft has sufficient function so that the recipient is **NOT** receiving any insulin or oral medication for blood sugar control
- **Partial Function:** The patient is taking some insulin, but $\leq$ 50% of the usual amount taken before transplant, or C-Peptide is present
- **Failed:** The graft has totally failed and the patient is completely dependent upon insulin or oral medication for blood sugar control

While reviewing the Tiedi help documentation, the Committee noted several deficiencies. These deficiencies of the pertinent section of the Tiedi guidance are that the help documentation:

- Conflicts with the definition of graft failure in policyIs not in the forefront of transplant professionals' minds since it is not located in policy
- Is unclear regarding amount or duration of insulin use
- Does not specify a c-peptide threshold nor does it address Type 1 vs. Type 2 diabetics

- Does not address the scenario where a patient taking oral medications only to support their glucose control is declared a failure, but is very uncommon that this scenario would be deemed a failure by the transplant center.

Further, since few centers utilize the "Partial Function" category on the OPTN pancreas forms, this suggests that the "Partial Function" category is either underutilized or unnecessary.

During the course of the project, the Committee also looked to other areas of policy for guidance on graft failure definitions. The Tiedi glossary defines graft failure as, "When organ removal, death, or replacement on chronic allograft support system has occurred." In addition, the current general definition for graft failure, as located in OPTN Policy, is, "Occurs when an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system." However, neither definition encompasses all situations for when a pancreas graft has failed. The Committee noted that the definition of graft failure for other organs is a terminal event, and in contrast, the Committee had to include gradual failure (i.e. the insulin category), in addition to complete failure.

During the project's development, the Committee noted that the general definition of graft failure, which is currently located in Policy 1.2 Definitions, needs an update. As part of this proposal, the Committee will gather suggestions for updates to the general definition of graft failure. Specifically, should there be a general definition of graft failure for all organs except for pancreas? Should there be a general definition of graft failure for some of the organs, and some of the organs have an organ-specific definition of graft failure? Should there be a separate organ-specific definition for graft failure for each organ? Feedback on these questions may be used for a separate proposal to update the general definition of graft failure in Policy 1.2.

The current general definition of graft failure is located in Policy 1.2 Definitions, and reads:

> **Graft failure**
> Occurs when an organ is removed, a recipient dies, or a recipient is placed on a chronic allograft support system.

In addition to drafting the definition of pancreas graft failure, the Committee cleaned up language in Policy 3.6.B.ii Non-function of a Transplanted Pancreas, to omit references to pancreas graft failure so that Policy 3.6.B.ii and the proposed definition of pancreas graft failure do not conflict. While redacting references to pancreas graft failure in the current Policy 3.6.B.ii language, the Committee discussed further potential policy language changes to Policy 3.6.B.ii. The Committee decided to table the discussion of potential, extensive, language changes to Policy 3.6.B.ii for a future date. The Committee made this decision because it did not want to expand the scope of definition for pancreas graft failure project. However, the Committee welcomes feedback from the pancreas transplant community as to whether Policy 3.6.B.ii Non-function of a Transplanted Pancreas needs extensive language changes and whether Policy 3.6.B.ii needs substantive changes to the meaning of the policy section.

- ***Collaboration:***

Although the definition of pancreas graft failure project was not a combined project with the MPSC, because the project directly effects MPSC's program assessments, the Committee has routinely kept the MPSC updated on the projects progress.

Two aspects of the proposed definition have caused significant discussion. The first aspect that has caused discussion is the insulin category within the proposed definition of pancreas graft

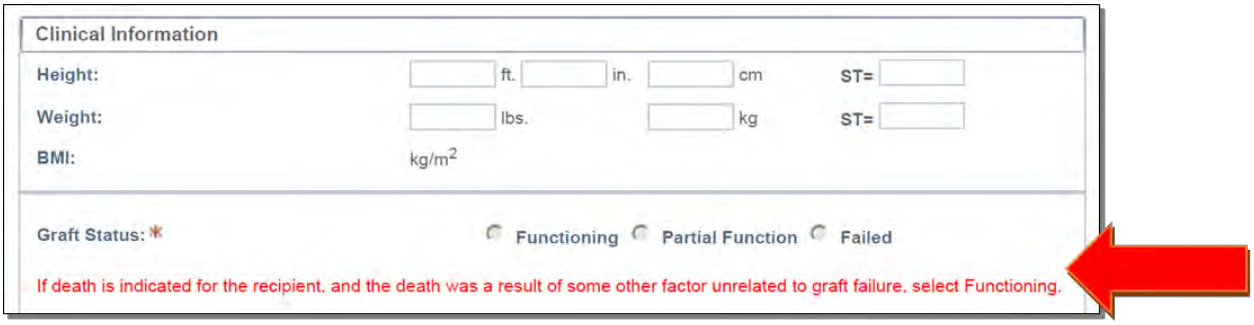
failure. The second aspect of the definition that has caused discussion is the recipient death category.

The proposed definition of pancreas graft failure states that a pancreas graft failure occurs when "A recipient's insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days". The insulin category of graft failure identifies situations where graft failure occurs gradually over time. Gradual pancreas graft failure caused a lot of discussion and negotiation amongst Committee members and interested parties (interested parties being pancreas transplant professionals who are not currently Committee members). Specifically, Committee members and interested parties debated over the amount of insulin that indicates pancreas graft failure. In the end, all parties agreed that 0.5 units/kg/day, over a consecutive, three-month time period indicates the graft failed. This is a conservative measure that the medical expertise agreed on as being an indicator that the graft has failed.

Recipient deaths also caused a lot of discussion. The proposed definition states that pancreas graft failure occurs when "[a] recipient dies". The Committee intends for the recipient death category to mean that a recipient died with a functioning pancreas allograft because a patient that dies with a failed pancreas allograft should already have been reported when the graft failed.

The discussion surrounding the recipient death category stems from instructional language that is currently located on the OPTN pancreas forms. Underneath the graft status section of the OPTN pancreas forms, instructional language, in red font, states: "If death is indicated for the recipient, and the death was a result of some other factor unrelated to the graft failure, select Functioning."

A screen shot of the pertinent section of the OPTN pancreas form is below. This screen shot is taken specifically from the adult pancreas Transplant Recipient Follow Up form (TRF) but the information in the screen shot is located in all the OPTN pancreas forms:



The OPTN pancreas forms retrospectively qualify the state of the pancreas at the time of death. This has been interpreted by some to mean death with a functioning graft does not constitute graft failure. The Committee supports collecting the status of the pancreas graft at the time of death, which is in conjunction with how the graft status data is currently reported on follow-up forms. At the same time, the Committee feels that the pancreas graft failure definition should include recipient death of all causes. As part of this proposal, the Committee recommends to make the following updates to the OPTN pancreas forms:

- Remove "Partial Function" graft status category
- Updating the instructional language, in red font
- Create additional fields for specific data collection that will allow for future enhancement to the pancreas graft failure definition

Regarding the instructional language in red, the Committee proposes to change the sentence to either:

- "If the recipient does not fall within one of the OPTN policy definition categories of pancreas graft failure, at the time of death, then report the graft as "Functioning", or
- If death is indicated for the recipient, report graft status up until the instance of death."

Further, the Committee proposes to update the Tiedi help documentation to also include instructional directions for when to select "Functioning" versus "Failed" for graft status.

- ***Alternatives considered:***

The Committee's first draft of the definition for pancreas graft failure was as follows.

> *Pancreas graft failure has occurred if a Type 1 diabetic pancreas recipient has:*
> - *a stimulated c-peptide less than 0.4 and is insulin dependent,*
> - *undergone a pancreatectomy,*
> - *been retransplanted, or*
> - *died*

One aspect of the first draft includes a c-peptide threshold that indicates pancreas allograft failure. However, Committee members questioned the validity of the c-peptide value, 0.4. As such, the Committee members performed a literature review to determine if current medical literature speaks to a c-peptide value that corresponds with pancreas allograft failure. The results of the literature review were inconclusive. In addition, the OPTN does not collect c-peptide values for pancreas transplant recipients either before transplant or at graft failure.

Therefore, the Committee decided to perform a C-peptide Data Collection Study in order to determine a c-peptide value that corresponds with pancreas allograft failure. (See Supporting Evidence and/or Modeling section for further discussion on the C-peptide Data Collection Study.)

- ***Strengths and weaknesses:***

The proposal's strength is that it creates a solution to a project that has been in existence and discussed for numerous years. The solution addresses a topic that is understandably unpopular in the community, yet necessary for the medical advancement of pancreas transplantation. Another strength is that the proposed solution creates a simple definition of pancreas graft failure that creates a straightforward evaluation of a transplant recipient's graft status where pancreas graft failure encompasses the fluctuating disease of diabetes - a disease that can morph from Type 1 diabetes to Type 2 diabetes in a single transplant and varies drastically depending upon patient compliance – the proposed definition attempts to create a uniform benchmark. At this time, there is not sufficient information and OPTN data available to draft a specific definition of pancreas graft failure, which addresses every situation in which a graft may fail for a Type 1 or Type 2 diabetic.

However, the proposed definition creates a strong infrastructure in which the Committee may expand upon, in the future, as information becomes available. From a different perspective, the benchmark definition creates an incomplete definition for pancreas graft failure. The proposed definition does not encompass all scenarios in which a transplanted pancreas may fail. However, the Committee acknowledges this point. The Committee chose to produce a benchmark definition at this time for two reasons:

(1) Timing:The Commiteee's proposal creates a pancreas graft failure definition that the MPSC may use to begin monitoring pancreas transplant centers in the relatively near future. This will allow the MPSC to monitor pancreas transplant outcomes.

(2) Need: The pancreas community needs a definition that can be applied consistently throughout the country. The Committee's proposed definition applies to all diabetes types and removes vagueness of partial function (as a currently available reporting field on the OPTN pancreas forms).One of the challenges of identifying and reporting pancreas graft failure is that a pancreas graft may gradually fail over time. The current guidance on how to document pancreas graft failure is unclear as to when to report graft failure when the graft gradually loses function.

- ***Description of intended and unintended consequences****:*

The intended consequences of this proposal are to produce a pancreas graft failure definition that the MPSC may use to collect data to monitor outcomes, as well as to educate and communicate to members what constitutes graft failure and how to document graft failure. The latter intended consequence will also allow members to consistently and uniformly document pancreas graft failure. In turn, such a consistent and uniform practice will produce accurate and reliable nationally reported data that ideally will allow the Committee, and pancreas community, to make the definition more specific in the future as well as gain more insight as to when graft failure occurs. Ultimately, a more detailed understanding of pancreas graft failure will lead to better graft management.

An unintended consequence is that the proposed definition will capture false graft failures or under report graft failures. The Committee plans to manage this unintended consequence by monitoring the graft failure outcomes data and to utilize the data, collected from the new fields on the OPTN pancreas forms, to draft a more specific definition of pancreas graft failure, in the future.

Supporting Evidence and/or Modeling:

As mentioned above, the first draft of the definition for pancreas graft failure included a c-peptide threshold. The Committee questioned the appropriateness of the c-peptide threshold, and when a literature review did not speak to what c-peptide threshold indicates pancreas allograft failure, the Committee performed its own c-peptide study.

The Committee performed a C-peptide Data Collection Study in order to determine a c-peptide value that corresponds with pancreas allograft failure. This data collection project consisted of collecting pancreas transplant recipients' c-peptide values at pre transplant, at return to insulin, and at graft failure. This purpose of the study was to allow members to determine the c-peptide value and methodology that indicates pancreas allograft failure.

The research plan was for each participating center to collect the past decade of pancreas transplant recipients' c-peptide values pre transplant and at graft failure. Then, the centers compiled the data and analyzed the results to determine if a c-peptide threshold was consistently used to indicate graft failiure or if c-peptide at graft failure could be predicated with pre transplant c-peptide. The study was limited by the only available indicator of graft function being graft status as reported on OPTN pancreas and kidney-pancreas registration and follow-up forms.

Study Structure

Seven centers submitted data for the C-peptide Data Collection Study. The data spanned over the last ten years of reported pancreas graft failures for pancreas or kidney-pancreas transplants since 2002 reported in OPTN database. The data were collected at the following points: pre-transplant, return to insulin, and graft failure. The data collected were c-peptide value, c-peptide type (fasting or stimulated), creatinine value, and corresponding measurement dates.

C-peptide Data Collection Study Results

The table below shows data compiled as voluntarily submitted by participating centers in the OPTN/UNOS Pancreas Transplantation Committee's Definition for Pancreas Allograft Failure Project. C-peptide data on pancreas recipients are not currently required by the OPTN.

Table 1. Empirical distribution of C-Peptide values pre-transplant, at insulin resumption, and at graft failure for data submitted through the Outcomes Subcommittee data collection project.

	N	Mean	SD	Min	25th Percentile	Median	75th Percentile	Max
Pre-Transplant C-Peptide	149	2.03	6.1	0	0.1	0.2	0.5	33
C-Peptide at Return to Insulin	94	2.28	2.2	0.1	0.6	1.46	3.4	12.1
C-Peptide at Graft Failure	233	2.11	3.3	0	0.4	0.9	2.7	33

Table 1 shows the empirical distribution of all c-peptide values submitted at each time point for this data collection project. Note that there is a large range from minimum to maximum, which speaks to insulin resistance. The table doesn't show results separated between Type 1 and Type 2 diabetics so any recipient with c-peptide less than or equal to one was considered a Type 1 diabetic by the Committee. This separation was understood when examining graphical representations of the data.

Table 2. Number of C-Peptide values pre-transplant, at insulin resumption, and at graft failure by encrypted transplant center for data submitted through the Outcomes Subcommittee data collection project.

	Pre-Transplant C-Peptide	At Return to Insulin C-Peptide	At Graft Failure C-Peptide	N With Both Pre-Transplant and at Graft-Failure C-Peptide	N With C-Peptide at all 3 points
Encrypted Center ID	**N Available**	**N Available**	**N Available**	**N Available**	**N Available**
23250	5	0	3	2	0
3410	2	3	4	0	0
6820	40	6	39	29	3
24800	22	22	17	2	2
7347	1	0	94	1	0
16957	21	7	19	19	7
7905	58	56	57	24	24
Total	149	94	233	77	36

Table 2 shows the volume of data queried and submitted by each center. Note the inconsistency on when transplant centers collect the c-peptide values.

Figure 1. Distribution of C-Peptide values pre-transplant for data submitted through the Outcomes Subcommittee data collection project.

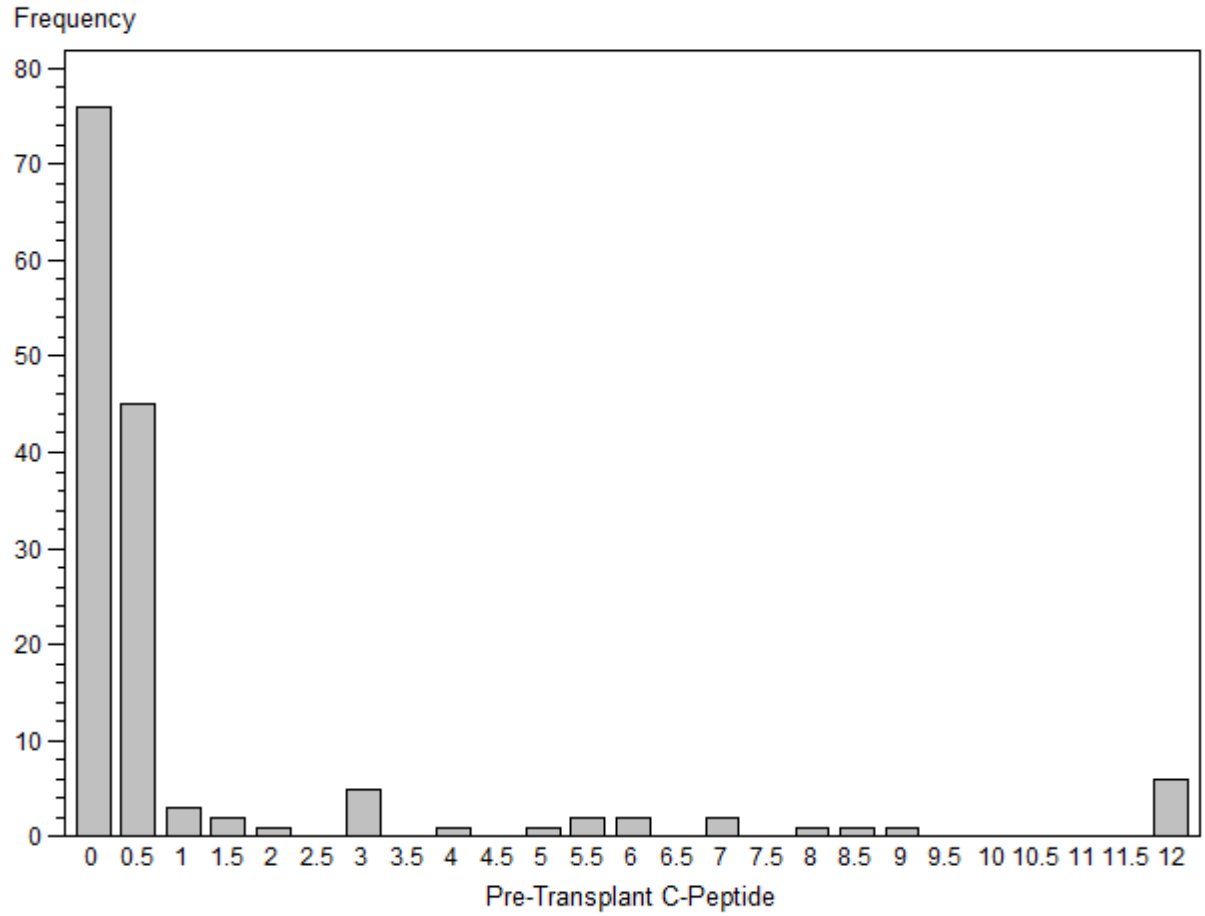


Figure 1 graphically shows the distribution of all pre-transplant c-peptide values submitted in this study. The majority of recipients had c-peptide less than 1 pre-transplant.

Figure 2. Distribution of C-Peptide values at insulin resumption (n=94) for data submitted through the Outcomes Subcommittee data collection project.

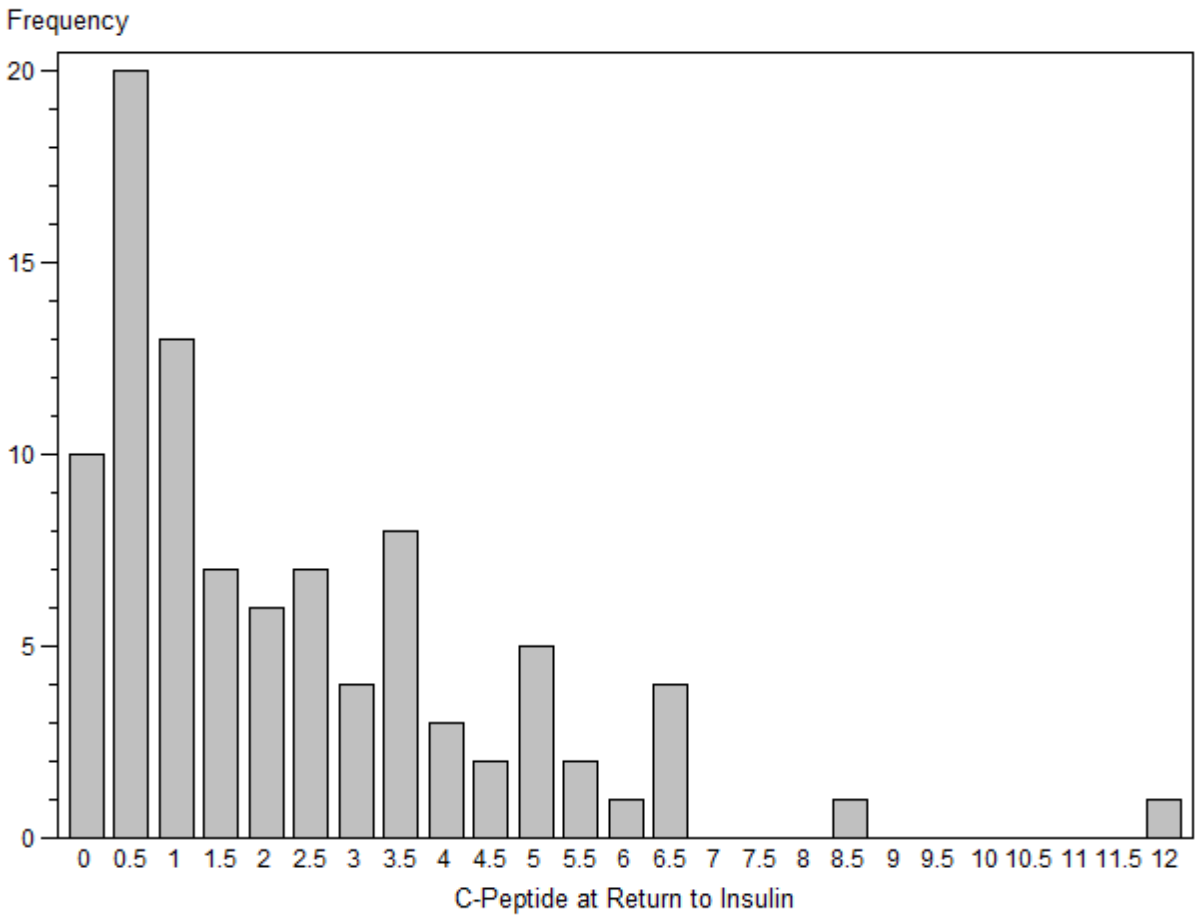


Figure 2 shows the distribution of all c-peptide values at return to insulin for this project. What this shows is that physicians are returning their patients to insulin at varying levels of pancreas function.

Figure 3. Distribution of c-peptide values at graft failure (n=233) for data submitted through the Outcomes Subcommittee data collection project.

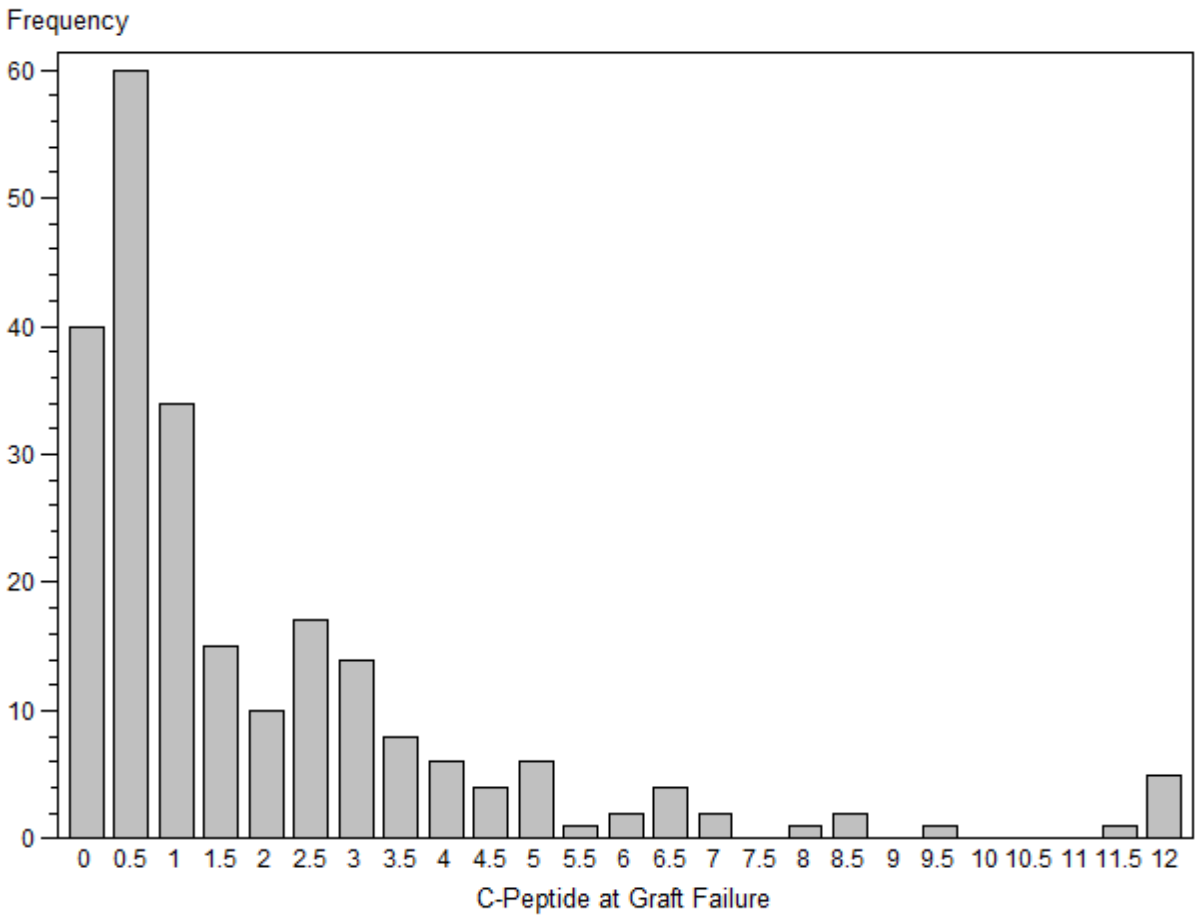


Figure 3 shows the distribution of all c-peptide values at graft failure submitted in this project. This distribution shows that transplant centers are calling a graft failed at varying levels of recipient c-peptide. However, this distribution is more right skewed, favoring smaller values, than the distribution at return to insulin.

Figure 4. Bivariate Distribution of c-peptide values pre-transplant and at graft failure (n=77) for data submitted through the Outcomes Subcommittee data collection project.

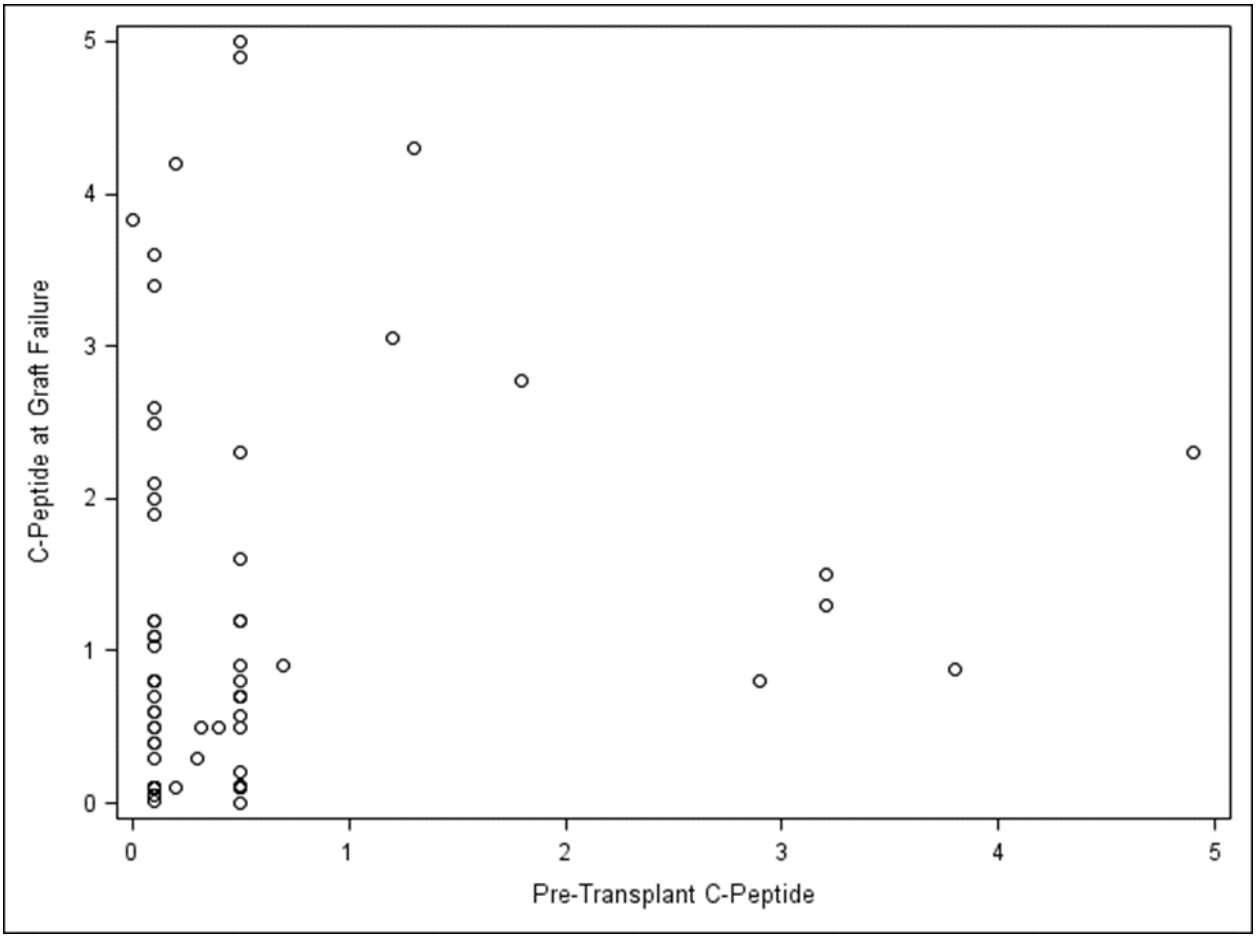


Figure 4 shows the bivariate distribution of all 77 pairs of pre-transplant and at graft failure c-peptide values. It is seen here that although most recipients had c-peptide less than 1 pre-transplant, their graft failure was claimed at varying levels of c-peptide.

Table 3. Number of c-peptide values pre-transplant, at insulin resumption, and at graft failure by encrypted transplant center for data submitted through the Outcomes Subcommittee's C-peptide Data Collection Project.

Encrypted Center ID	N Total Graft Failures	N With Both Pre-transplant and at Graft Failure C-Peptide	N With C-Peptide at All 3 Points	N with Pre-Transplant 0.75 or less and at Graft Failure Value Available
3410	14	0	0	0
6820	66	29	3	28
7347	94	1	0	1
7905	139	24	24	22
16957	21	19	7	7
23250	6	2	0	2
24800	75	2	2	1
Total	415	77	36	61

Table 3 shows the total number of graft failures that were voluntarily submitted for this study, the number with c-peptide values at pre-transplant and graft failure, as well as the number with measurements at all three points (pre-transplant, return to insulin, and at graft failure). Additionally, the last column shows the number of graft failures that were voluntarily submitted to this study with pre-transplant c-peptide less than or equal to 0.75 (likely the Type 1 diabetics) and with a graft failure c-peptide value available. There were 36 recipients with c-peptide collected at all three time points (pre-transplant, return to insulin, and at graft failure). Of these 36 recipients, 30 recipients returned to insulin at graft failure.

Figure 5. Distribution of c-peptide values of 1 or less at pre-transplant (n=77) for data submitted through the Outcomes Subcommittee's C-peptide Data Collection Project. Horizontal axis labels are midpoints.

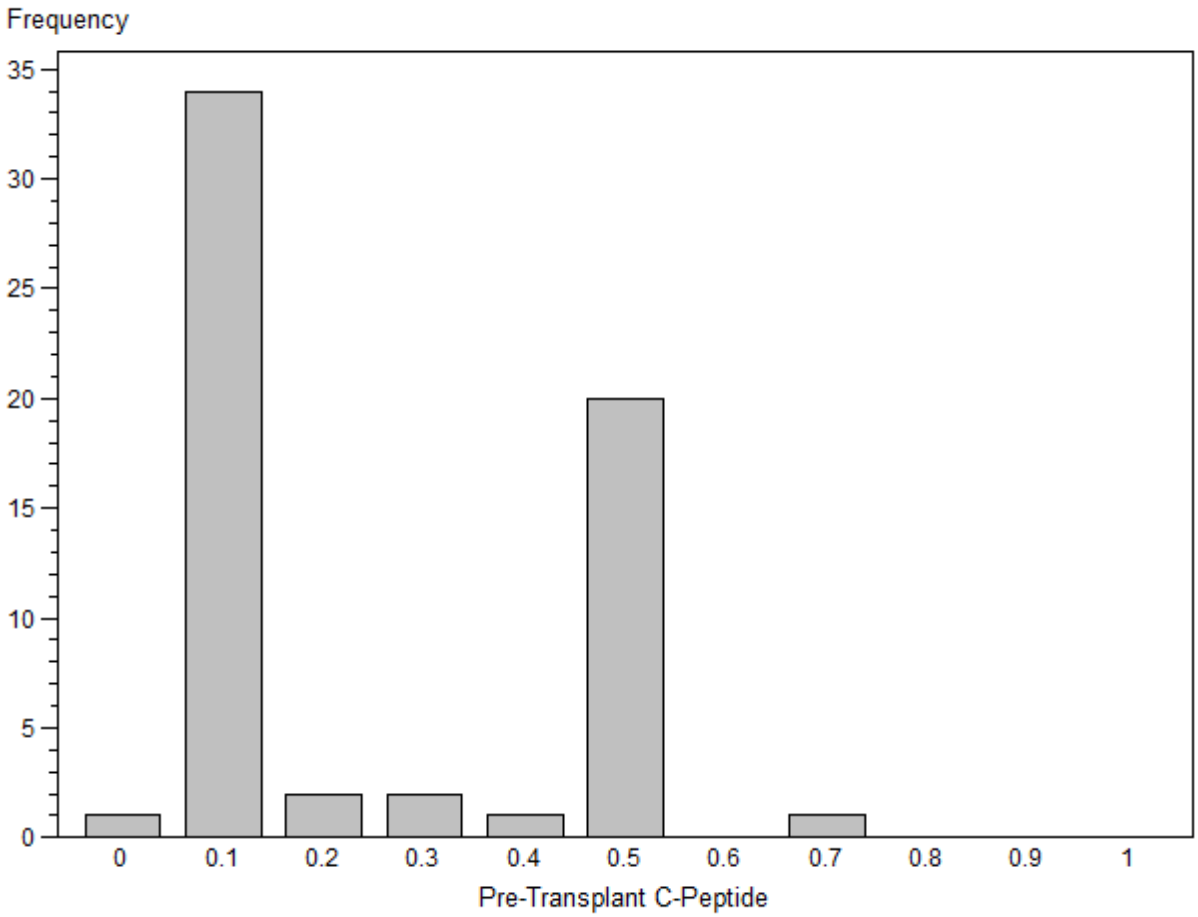


Figure 5 displays all pre-transplant c-peptide values submitted that are less than or equal to 1. The frequency in the bins containing 0.1 and 0.5 are due to the many submissions of values "<0.1" and "<0.5". Currently, some labs report c-peptide values at two values: <0.1" and "<0.5". This reporting practice should be considered when collecting c-peptide values on the OPTN pancreas forms.

Figure 6. Distribution of c-peptide values at graft failure for data submitted through the Outcomes Subcommittee's C-peptide Data Collection Project where both graft failure and pre-transplant c-peptide values were submitted (n=77). Horizontal axis labels are midpoints.

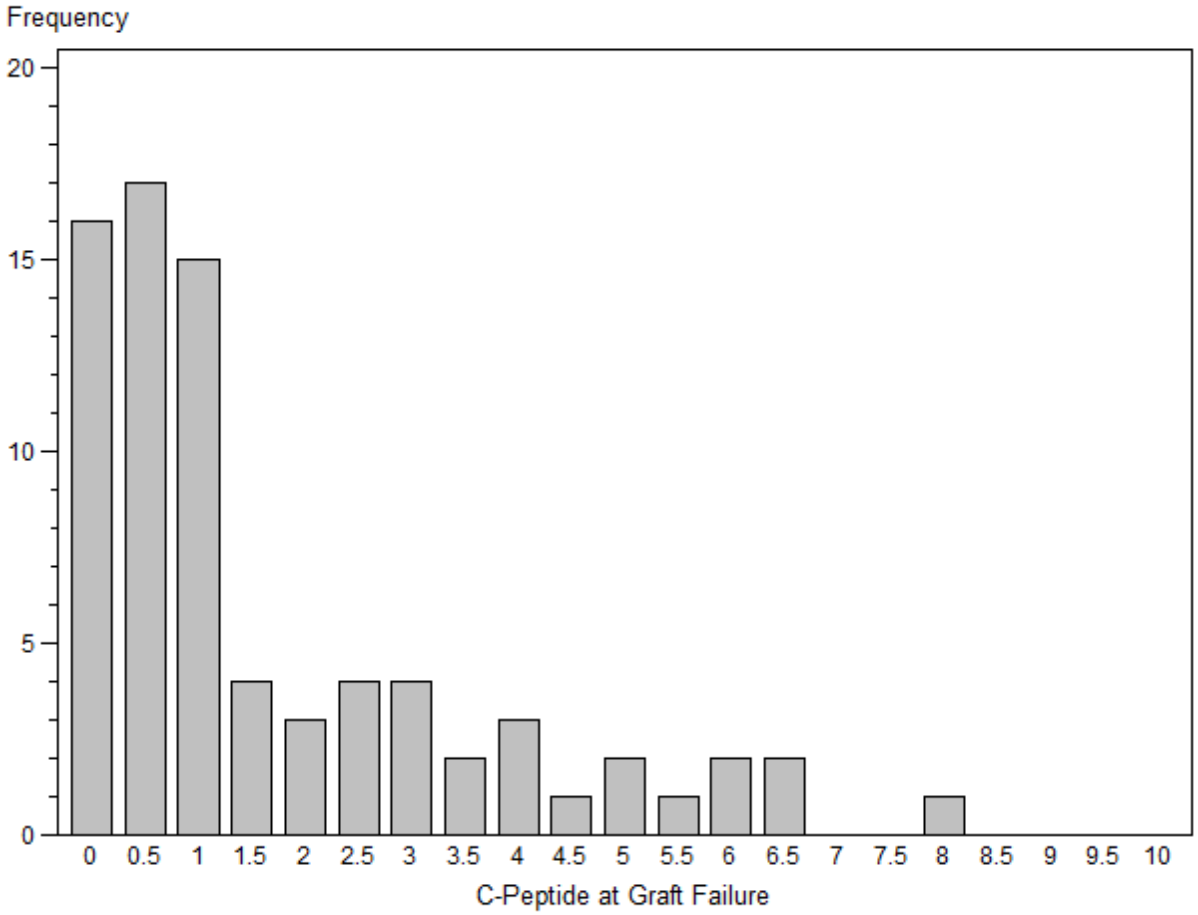


Figure 6 displays the distribution of c-peptide values at Graft Failure for all 77 graft failures that were submitted with both pre-transplant and graft failure c-peptide values.

Figure 7. Distribution of c-peptide values at graft failure for data submitted through the Outcomes Subcommittee's C-peptide Data Collection Project where both graft failure and pre-transplant c-peptide values were submitted and the pre-transplant value was 0.75 or less (n=61). Horizontal axis labels are midpoints.

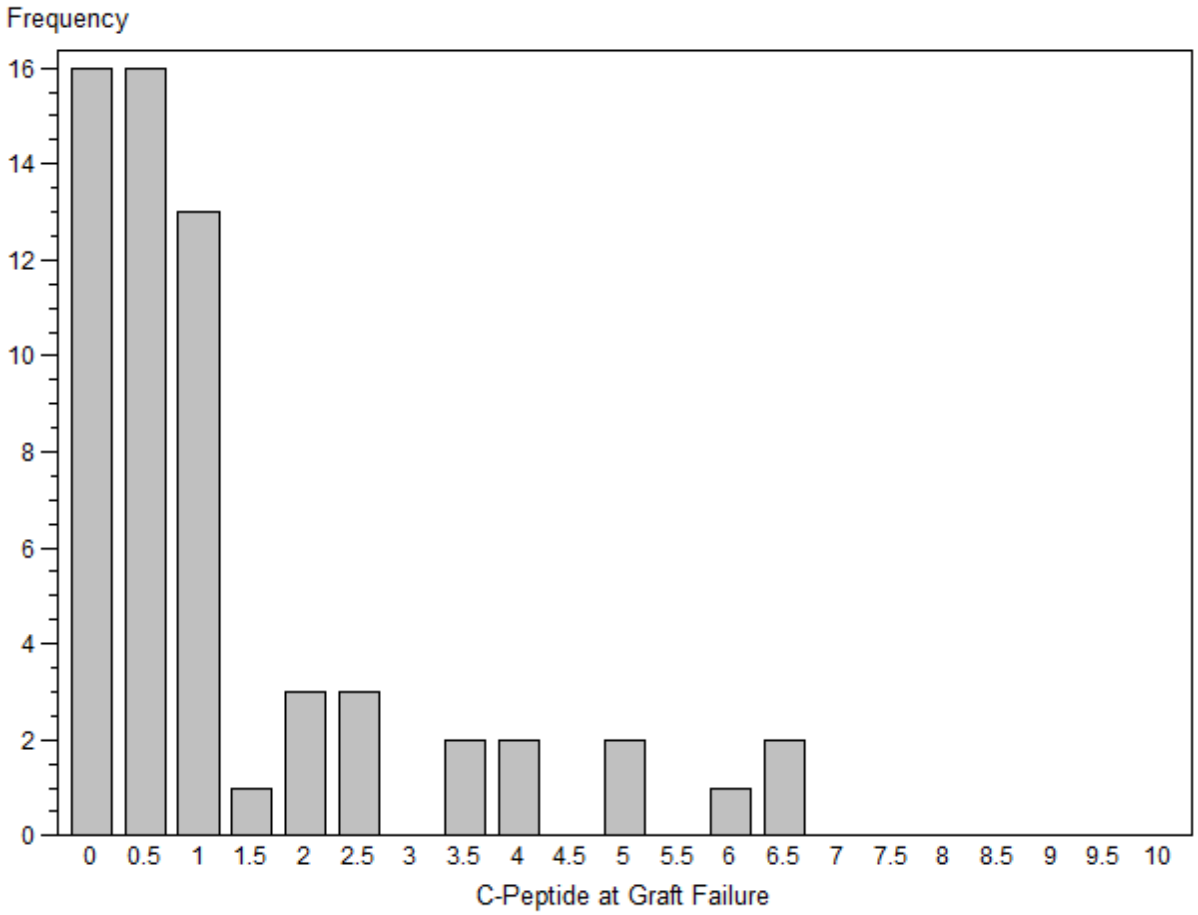


Figure 7 displays the distribution of c-peptide values at Graft Failure for all 61 graft failures that were submitted with both pre-transplant and graft failure c-peptide values where the pre-transplant c-peptide value was 0.75 or less. This distribution tends towards smaller values at graft failure in comparison to Figure 2 which contains all pairs of values. It is likely that those who had pre-transplant c-peptide of 0.75 or less are Type 1 diabetics, and the recipients with pre-transplant c-peptide values greater than 0.75 are predominantly Type 2 diabetics.

Figure 8. Bivariate Distribution of c-peptide values pre-transplant (0.75 or less) and available c-peptide value at graft failure (n=61) by whether the graft failure c-peptide was taken fasting for stimulated for data submitted through the Outcomes Subcommittee's C-peptide Data Collection project.

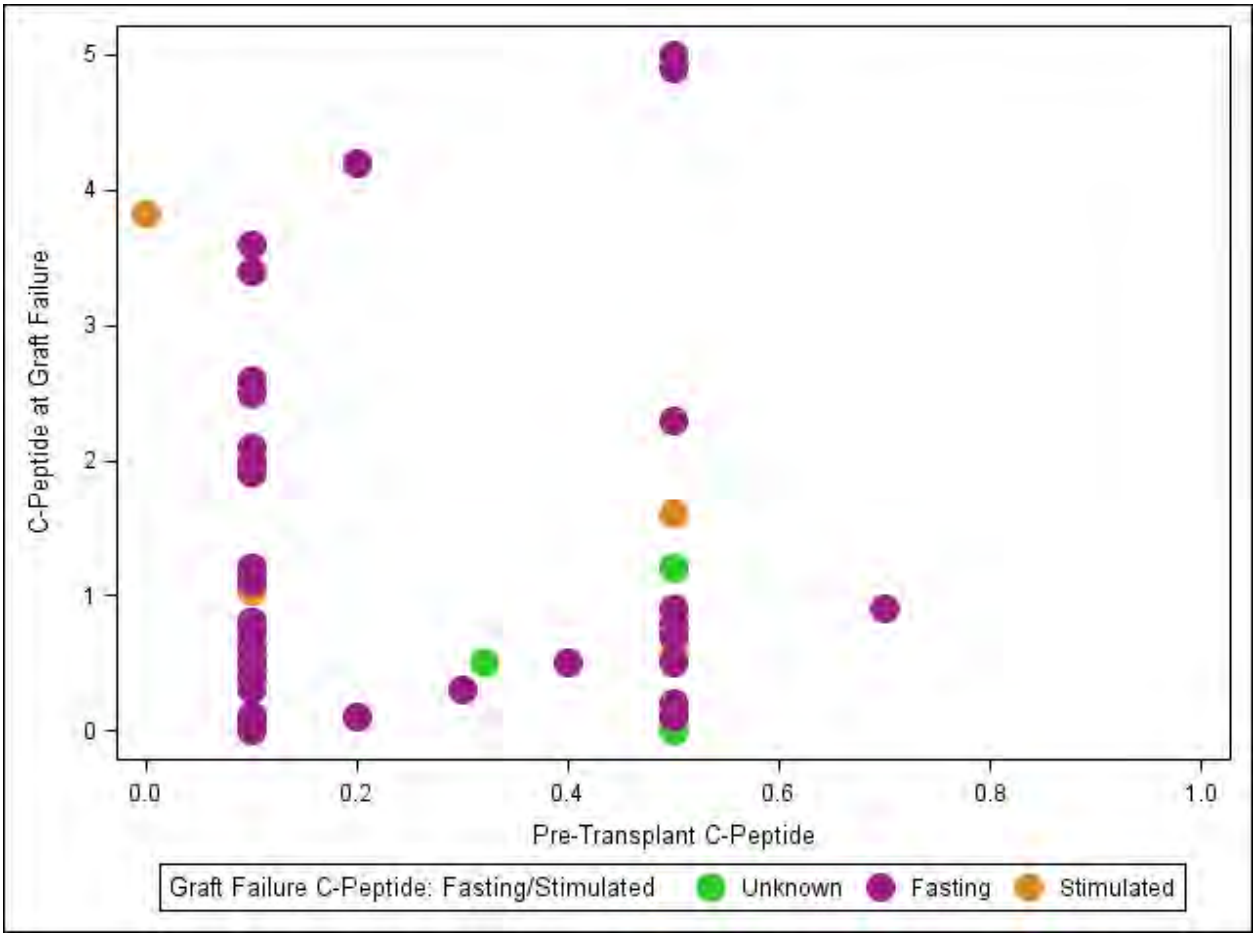


Figure 8 shows the bivariate distribution for the graft failures represented in this study with both pre-transplant and graft failure measurements with c-peptide at pre-transplant 0.75 or less by whether or not the value was taken fasting or stimulated. Of the 61 pairs, 3 graft failure values did not indicate whether they were fasting or stimulated, 4 were taken stimulated, and the other 54 were fasting. Even though there are small sample sizes, the fact that the higher values of c-peptide at graft failure were not biased by stimulated testing indicates that graft failure is not uniformly reported at any specific level of c-peptide.

Figure 9. Bivariate Distribution of c-peptide values pre-transplant (0.75 or less) and available c-peptide value at graft failure (n=61) by encrypted center for data submitted through the Outcomes Subcommittee's C-peptide Data Collection Project.

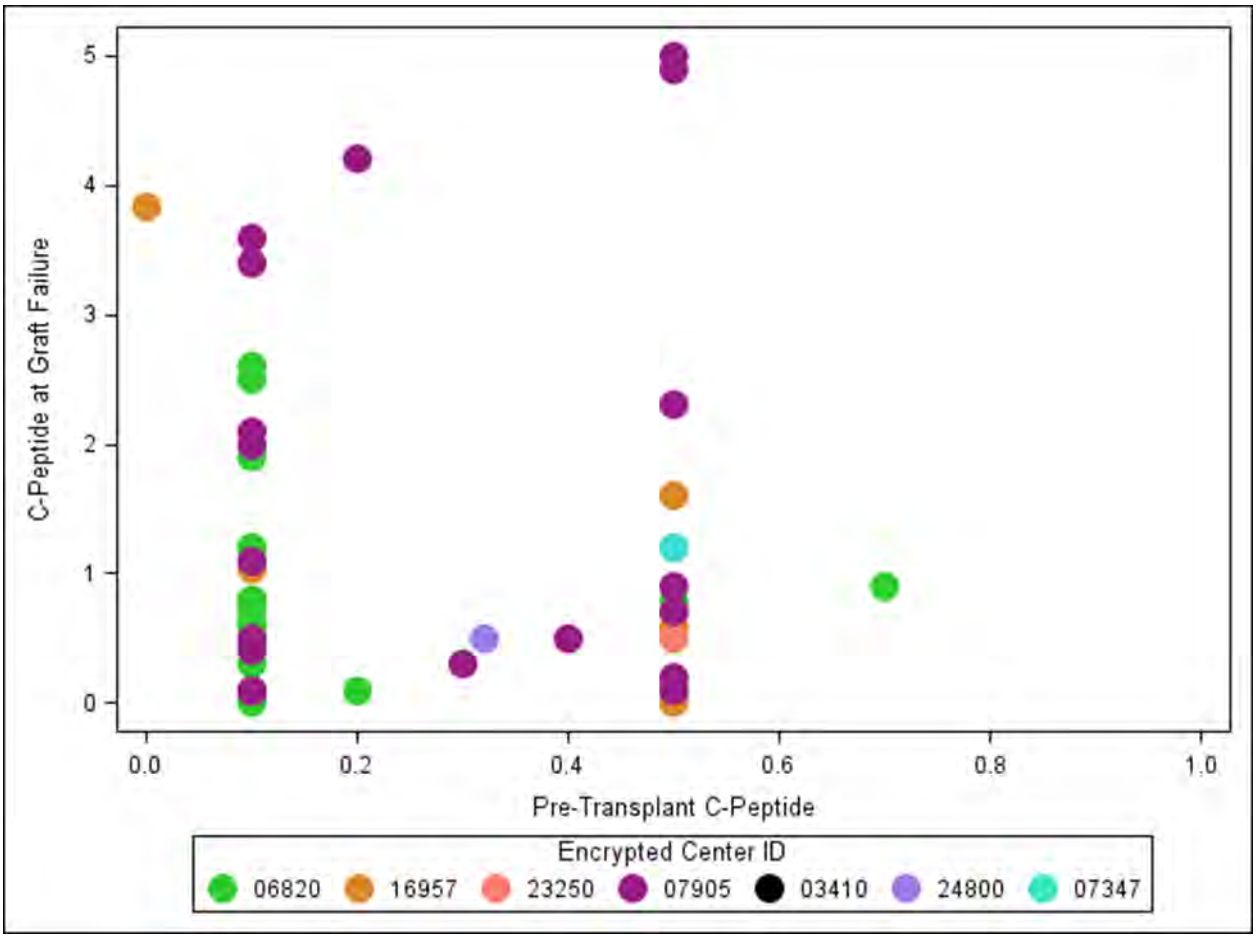


Figure 9 represents the bivariate distribution of all pairs of pre-transplant c-peptide values and c-peptide values at graft failure and the marker colors represent the centers that voluntarily submitted data as part of this project. It does not look like certain centers were reporting graft failures are higher levels than other centers.

The C-peptide Data Collection Study data presented here is compiled as voluntarily submitted by participating centers in the OPTN/UNOS Pancreas Transplantation Committee's Definition for Pancreas Allograft Failure Project. C-peptide data on pancreas recipients are not currently required by the OPTN.

C-peptide Data Collection Study Conclusions

The study results show that pancreas graft failure is reported at various levels of pancreas functioning. There is variation between centers in how they report graft failure as well as a variation from patient-to-patient.

It appears that there is not a consistent c-peptide threshold that surgeons use to determine when a pancreas failed. The data suggests the practice is more of a case-by-case situation used to determine when the graft failed.

The c-peptide levels show a large fluctuation, which implies differing levels of pancreas function at graft failure. Graft failure is being reported at all levels of c-peptide values and patients are being returned to insulin at all levels of c-peptide values. There is variation in what surgeons constitute pancreas graft failure, and suspected variation in what surgeons call return to insulin. Notably, the reason that the return to insulin endpoint is variable could in part account for some variability of the c-peptide at return to insulin. However, this last point is merely suspect at this time.

The SRTR notified the Committee that the SRTR has performed a separate research project on oral agent use, insulin use, and pancreas graft failure. This separate research project is an analysis of merged OPTN and IMS data that shows:

- Many patients are on insulin after transplant. Some of these are reported as graft failures, while others are not.
- There is not sufficient evidence for a dose-response relationship between insulin and kidney graft failure or patient death.

Furthermore, similar to the results of the C-peptide Data Collection Study that the Committee performed, SRTR's analysis supports the need for a uniform definition of graft failure. The Committee did not request nor review the results of SRTR's study. The Committee is aware of this separate research project, and based on general background of the project, decided it did not need to review the data in detail, on the separate SRTR project in conjunction with this proposal.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

The specific patient populations impacted by this proposal are those patients who have received or will receive a pancreas, pancreas after kidney, or simultaneous kidney-pancreas transplant. The expected impact on these specific patient populations is how their graft status, regarding graft failure, is documented may change. The documentation may change depending upon how the surgeon currently documents pancreas graft failure. Specifically, modifications to the OPTN pancreas forms may effect a patient depending on when a surgeon declares a patients' pancreas graft has failed.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

Pancreas transplant programs' graft outcomes cannot be accurately and fairly analyzed and compared against national expectations with the use of varying definitions for pancreas graft failure. A consistent definition will allow for graft outcome comparisons to a nationally derived expectation, which will promote transplant patient safety and improve post-transplant patient survival. Specifically, consistently and nationally reported pancreas graft failure data will strengthen the validity of future outcomes studies because the study results will be based on uniformly reported data.

Plan for Evaluating the Proposal:
After the proposal goes into effect and there is a sufficient follow-up time period the Committee will evaluate submitted data and center reporting every six months during the first year and

potentially annually for several years thereafter. The Committee will be looking at the parameters reported on the OPTN pancreas forms as well as the graft outcomes as reported by centers. The Committee will ask questions when analyzing and determining reporting trends. These questions will include but are not limited to:

- How is the pancreas graft failure definition fairing in practice?
- Are centers' graft survival data dramatically changing?
- Evaluate the values of c-peptide, HbA1c, and insulin use reported on OPTN adult and pediatric pancreas and kidney-pancreas Transplant Recipient Registration Form and Transplant Recipient Follow-up Form in conjunction with which follow-up form is being report (i.e. at graft failure, death, or routine follow-up) Are the OPTN pancreas forms being submitted incompletely?
- Does reporting of graft failure vary by center based on pancreas and kidney-pancreas recipient characteristics (i.e. BMI, c-peptide, insulin use, HbA1c)
- Does graft failure reporting vary by individual patient categories, such as age, gender, ethnicity, highly sensitized, geographic location.

Notably the Committee will be simultaneously evaluating impacts from changes to the pancreas allocation system as well as impacts from this proposal.

Additional Data Collection:

Additional data collection will be required because of the proposal's policy change. There will be additional fields added to the adult and pediatric pancreas and kidney-pancreas OPTN Data Collection Forms. Specifically, the following fields will be added to the Transplant Candidate Registration Form (TCR), Transplant Recipient Registration Form (TRR), and Transplant Recipient Follow-up Form (TRF) for pediatric and adult pancreas and kidney-pancreas candidates/recipients:

- Fasting C-peptide serum level (ng/ml)
- HbA1c (%)
- Insulin use – amount per kg/day and duration of use

These additional fields will be required on the pancreas and kidney-pancreas registration or follow-up forms solely when a patient is alive with a functioning pancreas graft.

The additional fields support the Principles of Data Collection in that the additional fields will allow further development of transplant policies. As acknowledged, the proposed definition of pancreas graft failure is a starting point. Due to the lack of national and consistent information available about what constitutes pancreas graft failure, the Pancreas Transplantation Committee chose to propose a basic definition at this time. The intent is that in the future, the definition may evolve and become more specific. Therefore, the additional data fields will provide the Pancreas Transplantation Committee the information it needs to develop a more specific definition of pancreas graft failure, in the future.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect September 1, 2015.

In order to comply with the policy change a transplant center will need to be aware that a definition for pancreas graft failure exists in policy, be aware of the changes to the pancreas OPTN Data Collection Forms, and how the two changes interact. A transplant center will need to understand what constitutes pancreas graft failure, and how to fill out the graft status section of the pancreas OPTN Data Collection Forms.

Further, the transplant center should be aware there would be additional fields in the pancreas OPTN Data Collection Forms and the transplant center will be required to provide information in the additional fields when filling out the forms.

Communication and Education Plan:

This proposal will require a policy modification and changes to Tiedi forms. This proposal will be monitored for specific instructional needs. A small instructional program may likely be needed prior to the implementation of changes to Tiedi forms.

The specific Communication and Education efforts associated with the proposal are listed below.

Communication & Education Activities

- Policy notice
- System notice
- E-newsletter/member archive article
- Presentation at Regional Meetings
- Formal training (e-modules, Live Meetings, Webinars, etc.)
- Articles/Guidance Documents on the Web and Member Archive

Compliance Monitoring:

Based upon the proposed language, members will be expected to accurately report graft failure. However, the proposed language will not be added to the current routine monitoring of pancreas programs. Any data entered in UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested.

This proposal will improve the quality of the data available to the SRTR for analysis of program graft survival and production of the reports used by the Membership and Professional Standards Committee in its post-transplant performance reviews.

Policy or Bylaw Proposal:

1.2 Definitions

G

Graft failure
For all organs except pancreas, graft failure o~~O~~ccurs when *any* of the following occurs:

- ~~an~~ A recipient's transplanted organ is removed~~,~~
- ~~a~~ A recipient dies~~,~~
- ~~or a~~ A recipient is placed on a chronic allograft support system~~.~~

Pancreas graft failure occurs when *any* of the following occurs:

- A recipient's transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient's insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

3.6 Waiting Time

3.6.B.ii Non-function of a Transplanted Pancreas

Immediate and permanent non-function of a transplanted pancreas is defined as ~~pancreas graft failure requiring the~~ removal of the transplanted pancreas within ~~the first~~ 14 days ~~of~~ after transplant.

Pancreas waiting time will be reinstated when the OPTN Contractor receives a completed *Pancreas Waiting Time Reinstatement Form* and *either* of the following:

- An operative report of the removal of the pancreas.
- A statement of intent from the transplant hospital to remove the transplanted pancreas, and a statement that there is documented, radiographic evidence indicating that the transplanted pancreas has failed.

The transplant hospital must maintain this documentation. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

At-a-Glance

Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates

- **Affected/Proposed Policy:** No policies are affected by this proposal

  Thoracic Organ Transplantation Committee

  Extracorporeal membrane oxygenation (ECMO) has become a more common treatment for patients with end-stage lung disease awaiting lung transplantation. However, the Thoracic Committee has been unable to consider the impact of ECMO support on lung allocation because this information is not routinely collected and reported to the OPTN. The Thoracic Committee proposes the collection of ECMO information at the time of waiting list removal to retrospectively capture each candidate's mechanical ventilatory support history. This will provide the Thoracic Committee with data on a contemporary cohort of candidates in order to appropriately analyze how ECMO should be incorporated into the LAS calculation.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors

- **Number of Potential Candidates Affected**
  Transplant programs will be required to submit this information upon waiting list removal for each lung candidate. In 2013, 2,434 lung candidates were removed from the waiting list. If ECMO is ultimately incorporated into the LAS, it could affect the entire lung transplant waiting list.

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal furthers the OPTN Strategic Goal of improving survival for patients with end stage organ failure by better matching donated organs to recipients by collecting data to fully understand the medical condition of candidates transplanted while supported by ECMO.

  This proposal also furthers §121.8 of the Final Rule, which states: "(a) the Board of Directors…shall develop…policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies: (1) Shall be based on sound medical judgment; … (6) Shall be reviewed periodically and revised as appropriate". Collecting ECMO data will assist the Thoracic Committee in further refining the LAS based on contemporary objective medical evidence. It will also assist the Thoracic Committee in reviewing the LAS to ensure that it properly accounts for the medical condition of candidates supported by ECMO during their time on the waiting list.

Proposal to Collect Extracorporeal Membrane Oxygenation (ECMO) Data Upon Waitlist Removal for Lung Candidates

Affected/Proposed Policy: No policies are affected by this proposal.

Thoracic Organ Transplantation Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

Extracorporeal membrane oxygenation (ECMO) has become a more common treatment for patients with end-stage lung disease awaiting lung transplantation. The Thoracic Committee has been unable to consider the impact of ECMO support on lung allocation because this information is not routinely collected and reported to the OPTN. The Thoracic Committee proposes the collection of ECMO information at the time of waiting list removal to retrospectively capture each candidate's mechanical ventilatory support history. This will provide the Thoracic Committee with data on a contemporary cohort of candidates in order to appropriately analyze how ECMO should be incorporated into the LAS calculation.

Background and Significance of the Proposal:

The Lung Subcommittee of the Thoracic Committee began discussing ECMO data collection during an August 2012 teleconference in response to the following email from a member:

> A question came up…regarding policy for lung candidates who are supported with ECMO prior to transplant. Many centers…don't adjust the scores when patients' FIO_2 comes down on ECMO or claiming it's equivalent to being on 100% O_2 so the LAS remains high. Other centers are keeping their high scores from ventilation with high FIO_2 claiming they don't have to update for two weeks. As we have talked about in past meetings, there was no ECMO data in the set used to build the LAS and the odds ratio for acute mortality is extremely high in the UNOS data, so is it your feeling that it is OK for centers to simply come up with the highest score they can?

The member's email highlighted two separate problems related to reporting ECMO use in lung transplant candidates: 1) there are differences in how transplant programs report ventilatory support while on ECMO through the "continuous mechanical ventilation" field in Waitlist[SM]; and 2) there is a lack of data to analyze whether the LAS system appropriately calculates a score for candidates supported by ECMO prior to transplant.

The Lung Subcommittee addressed the inconsistent reporting problem first. Currently, transplant programs must report the candidate's ventilation status as "BiPAP," "CPAP," "continuous mechanical," "intermittent mechanical," and "no assisted ventilation needed." Transplant programs must also report whether the candidate requires supplemental oxygen, and the possible selections are "at night," "at rest," "with exercise only," and "not needed." The program must also input the amount of oxygen the candidate requires, either as a percentage or as liters per minute.

The Subcommittee ultimately determined that candidates who are extubated and on ECMO should be reported as on "continuous mechanical ventilation," with 100% oxygen. The Lung

Subcommittee decided upon 100% oxygen because candidates on ECMO are effectively ensured maximal oxygenation via the membrane oxygenator, and it ensures that these candidates will receive the highest calculated LAS based on their reported information. The Thoracic Committee approved the Lung Subcommittee's recommendation and distributed a memo to all lung transplant programs in February 2013 entitled "Reporting for Lung Transplant Candidates Supported by ECMO." Despite the distribution of the memo, there is no way to assure that transplant programs are consistently reporting this data, and reporting ECMO use is still not mandatory.

The Lung Subcommittee then turned its attention to the other problem: lack of information about candidates supported by ECMO prior to transplant. The OPTN does not currently collect these data because ECMO is not a variable in the LAS calculation. The Thoracic Committee did not include ECMO in the modified version of the LAS adopted by the Board of Directors in November 2012 because there were no ECMO data on waiting candidates.[1] Though the LAS modification was adopted, the American Society of Transplantation, during the public comment period noted "there should be some other considerations," stating, "Inclusion of ECMO was not considered into the model on the post-transplant side." OPTN/UNOS Board members also commented on the importance of collecting ECMO data during the November 2012 Board of Directors meeting. Since the November 2012 Board of Directors meeting, other members of the lung transplant community have noted the absence of ECMO in the LAS, and argued that "[t]he uncertainty regarding ECMO benefits raises ethical concerns about organ waste and preferential use of marginal allografts or cadaveric lobar transplants."[2]

The Lung Subcommittee defined two goals in collecting ECMO data: 1) ensure that candidates supported by ECMO receive an LAS that reflects the severity of their condition; and 2) capture data on a contemporary cohort of lung candidates treated with ECMO to inform future versions of the LAS calculation. These data will also help to identify candidates who are potentially too sick to be transplanted and to assess national trends in ECMO use.

Proposed ECMO Data Points

After determining that additional data collection is required, the Lung Subcommittee debated the specific data elements that should be reported. The Lung Subcommittee favored data collection that included variables likely to help differentiate candidates based on medical urgency in the future. An explicit goal is to use the information on ECMO to further refine the LAS, so collected data must be of sufficient granularity to further stratify candidates that are supported by ECMO and/or mechanical ventilation.

The Lung Subcommittee agreed upon collecting the dates of cannulation/intubation and decannulation/extubation, if applicable, for each ECMO device or mechanical ventilatory support device used to support the candidate while on the waitlist. These data will help determine whether waiting list mortality or post-transplant survival are affected by ECMO use at any time while waiting for transplant, or if only recent ECMO use is relevant.

[1] Alcorn, James B., "Summary of actions taken at OPTN/UNOS Board of Directors Meeting (November 12-13, 2012) and OPTN/UNOS Executive Committee Meetings (August 28, 2012; October 19, 2012; and November 12, 2012)." December 3, 2012. http://optn.transplant.hrsa.gov/ContentDocuments/2012-12_Policy_Notice.pdf.

[2] Venado, Aida, Charles W. Hoopes, and Enrique Diaz-Guzman, MD. "Prolonged extracorporeal membrane oxygenation use as a bridge to lung transplantation: It is time for a national registry", *Chest Journal* 145(1) (2014):184-185. Accessed August 11, 2014. doi:10.1378/chest.13-1851.

The Subcommittee debated whether to collect information on the site of cannulation (peripheral or central), and ultimately determined it is appropriate to collect this information because it is likely to be predictive of waiting list and post-transplant outcomes. Additionally, the Lung Subcommittee determined that the ambulation status of ECMO and mechanically ventilated patients may be an important variable, or relevant surrogate, in the determination of risk.

The Subcommittee also discussed whether it is important to collect the type of ECMO used to support a candidate. It determined that distinguishing candidates supported by veno-venous (VV) ECMO from candidates supported by veno-arterial (VA) ECMO is likely to be relevant in determining how to incorporate ECMO into the LAS calculation. Lung Subcommittee members noted that based on clinical experience, there is a significant difference in the medical condition of candidates placed on VV ECMO as opposed to VA ECMO. Though ECMO technology is rapidly evolving, the Subcommittee agreed that these two broad categories should capture most, if not all, future ECMO types as well.

The Lung Subcommittee debated whether to permit a transplant program to report ECMO use as "unknown" type in the device type field. The Lung Subcommittee ultimately determined that selecting "unknown" was ambiguous and may lead to inaccurate data reporting.

The Lung Subcommittee does not believe it is necessary to collect information on whether the ECMO unit is driven by a pump; nor is it necessary to collect information regarding the ECMO device brand or connection type (such as pulmonary artery to left atrium). The Lung Subcommittee believes that the basic information regarding device type will be sufficient for the purposes of analysis for potential inclusion in future versions of the LAS without the added complexity of additional data entry.

Though the Committee wants to keep the data entry as simple as possible while still collecting ample data to assess risk stratification amongst lung transplant candidates supported by ECMO, the Committee is mindful that other data variables may affect a candidate's condition while the candidate is supported by ECMO, including flow rates, sweep gas flow rates and fraction of delivered oxygen (F_DO_2). However, the Committee was concerned that variability in these parameters driven by physiological changes would not be adequately or accurately captured with the periodic data reporting required for waitlisted candidates.

Mechanism for Collecting ECMO Data

Lastly, the Lung Subcommittee discussed the best mechanism to collect the data. The Lung Subcommittee discussed developing a policy change requiring transplant programs to report ECMO information in a manner similar to that used for all LAS variables. Current policy requires transplant programs to report data relevant to the calculation of the LAS every six months, with the exception of certain variables that must be updated every 14 days in some circumstances. The transplant program is not required to provide retrospective data reflecting the whole reporting period; rather, the transplant program submits a "snapshot" of data that meets the reporting requirements. A candidate could go on and off ECMO within the reporting period, and the transplant program would not be required to report that the candidate was ever on ECMO during that period, and therefore would fail to capture all the information the Lung Subcommittee seeks.

The Lung Subcommittee also considered requiring all candidates on the waiting list supported by ECMO to apply to the Lung Review Board (LRB) for an LAS exception in order to capture the data. The Subcommittee, however, realized that candidates on ECMO are likely to already have

high LAS scores and their physicians will be unlikely to be motivated to request approval from the LRB for a higher LAS. A targeted data collection study is also unlikely to yield numbers necessary to properly analyze the effect of ECMO on waiting list and post-transplant survival. Because the number of candidates on ECMO may be relatively small, data on all candidates supported by ECMO, not just a sample of those candidates, is required in order to have sufficient information to analyze the effect of ECMO.

ELSO (Extracorporeal Life Support Organization) is an international registry that maintains "a registry of, at least, use of extracorporeal membrane oxygenation in active ELSO centers."[3] The Lung Subcommittee considered the feasibility of requesting data from ELSO to support policy development, but ultimately determined this would also be an inadequate solution. A significant number of lung transplant programs are not members of the ELSO registry. Therefore, a significant portion of the lung transplant population that may potentially be treated with ECMO would not be included in the data provided by the ELSO registry. Additionally, the ELSO database registers patients that have received ECMO but were never registered on the waiting list. These patients would not be relevant to the analysis the Lung Subcommittee must perform. Therefore, despite the ELSO registry, some in the transplant community agree that "[e]stablishment of a registry for [use of ECMO as a bridge to lung transplant] will be vital to systematically track practices, correlate outcomes, and establish standards of care."[4]

The Lung Subcommittee therefore recommends collecting information on mechanical ventilatory support devices, including ECMO, used to support the candidate at the time the candidate is removed from Waitlist[SM]. This would mimic the data reporting requirements for mechanical circulatory support devices for heart candidates. Transplant programs will be required to report all instances in which the candidate was supported by a mechanical ventilatory support device throughout their time on the waitlist. This approach will allow the Subcommittee to collect the most complete data possible for all candidates. Another benefit of this approach is that it will keep heart, lung, and heart-lung data collection as consistent as possible, making it easier for transplant programs to navigate and complete the forms.

The Lung Subcommittee thoroughly debated the costs of each option, including the cost of programming these fields on the upon waitlist removal, and concluded that programming these changes is the only way to ensure complete and accurate reporting for all lung transplant candidates. Additionally, the UNOS IT Department determined that the cost of programming, though large, is significantly lower than the original estimate presented to the Policy Oversight Committee and Executive Committee in March 2014.

On August 25, 2014, the Thoracic Committee voted to distribute this proposal for public comment. (18 support; 0 oppose; 0 abstained)

Supporting Evidence and/or Modeling:

ECMO use at the time of listing is currently collected on the Transplant Candidate Registration (TCR) form, and ECMO use at the time of transplant is currently collected on the Transplant Recipient Registration (TRR) form. ECMO data obtained from these forms may not reflect the entire population of lung candidates supported by ECMO, as ECMO use may be initiated after

[3] http://wwv.elso.org/about (Accessed on 8/7/2014)

[4] Fadul, RA, Budev, MM, McCurry, KR, Yun, JJ. "Extracorporeal Membrane Oxygenation (ECMO) Practices for Bridging to Lung Transplantation in North America: A Multicenter Survey." *Journal of Heart and Lung Transplantation*, 32:4S (2014): S246-S247. Accessed on September 2, 2014. doi: 10.1016/j.healun.2014.01.644.

listing but withdrawn prior to the candidate's removal from the Waitlist. The Lung Subcommittee nevertheless reviewed the data that are available.

Figure 1 reveals that use of ECMO is growing, with the percentage of candidates on ECMO at transplant more than tripling between transplants in the first half of 2010 compared to the first half of 2013 (0.9 percent vs. 3.5 percent). A survey conducted in 2014 to "better define the current use of ECMO as a bridge to transplant" revealed that "a significant proportion of US lung transplant programs use ECMO as a bridge to transplant."[5] As ECMO use continues to increase in bridging end-stage lung disease candidates to transplant, the Lung Subcommittee recognizes the need to collect more ECMO data to determine how to incorporate it into the LAS.

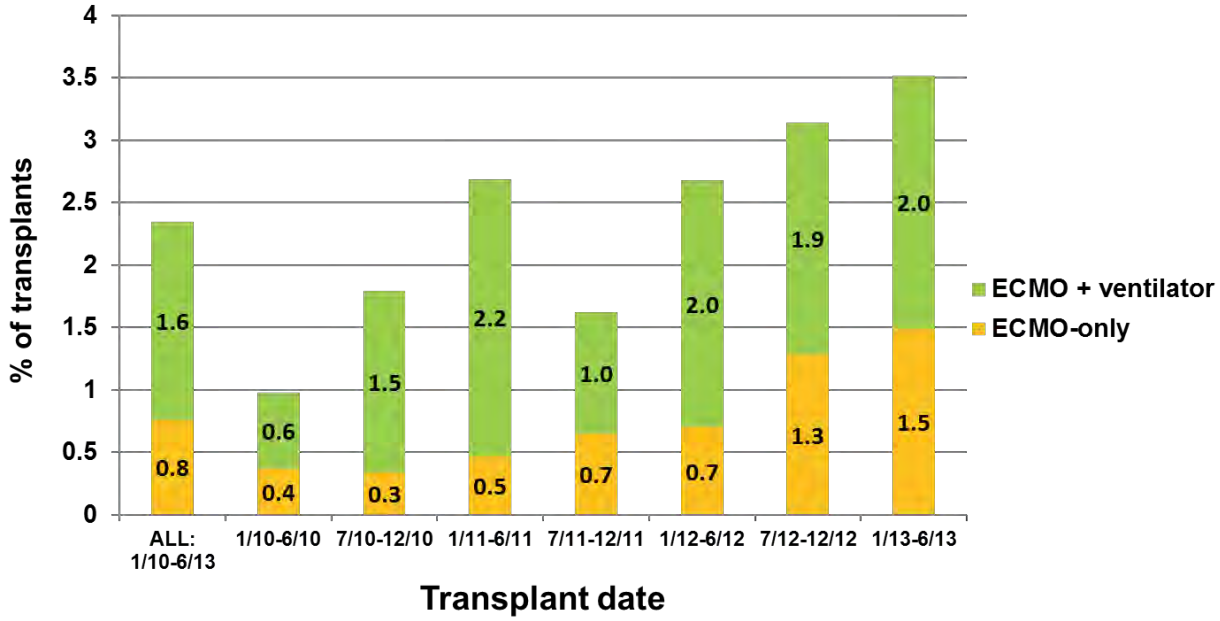


Figure 1: ECMO Use at Transplant

The Lung Subcommittee also reviewed data to determine whether certain factors reported in Waitlist[SM] could have contributed to differences in LAS at transplant based on the device at transplant (ECMO or ventilator). The data show that recipients on ECMO at the time of transplant had higher oxygen use at rest, required more help with activities of daily living (ADLs), and were more frequently on assisted ventilation. Over 80 percent of the recipients on ECMO at transplant were reported to be on 100 percent oxygen at rest on the waiting list, compared to 20 percent of those on a ventilator at transplant. All of these factors contribute to a higher LAS for recipients on ECMO at the time of transplant. There may be an effect of high LAS at transplant for ECMO patients, as one study revealed that "high acuity patients (LAS score >50) within our institutions who require and ECMO bridge were at a survival disadvantage compared with high acuity patients (LAS score >50) who did not require mechanical support."[6]

[5] Fadul, et.al, "Extracorporeal Membrane Oxygenation (ECMO) Practices for Bridging to Lung Transplantation in North America: A Multicenter Survey."

[6] Hoopes, Charles W., Kukreja, J., Golden, J., Davenport, D.L, Diaz-Guzman, E., and Zwischenberger, J.B. "Extracorporeal membrane oxygenation as a bridge to pulmonary transplantation." *The Journal of Thoracic and Cardiovascular Surgery*, 145:3 (2013): 862-868. Accessed August 11, 2014. DOI: 10.1016/j.jtcvs.2012.12.022

Additionally, Figure 2 shows those candidates supported by ECMO and a ventilator at the time of transplant have a notably lower one year post-transplant survival rate than recipients who were supported by ECMO only, a ventilator only, or neither device.

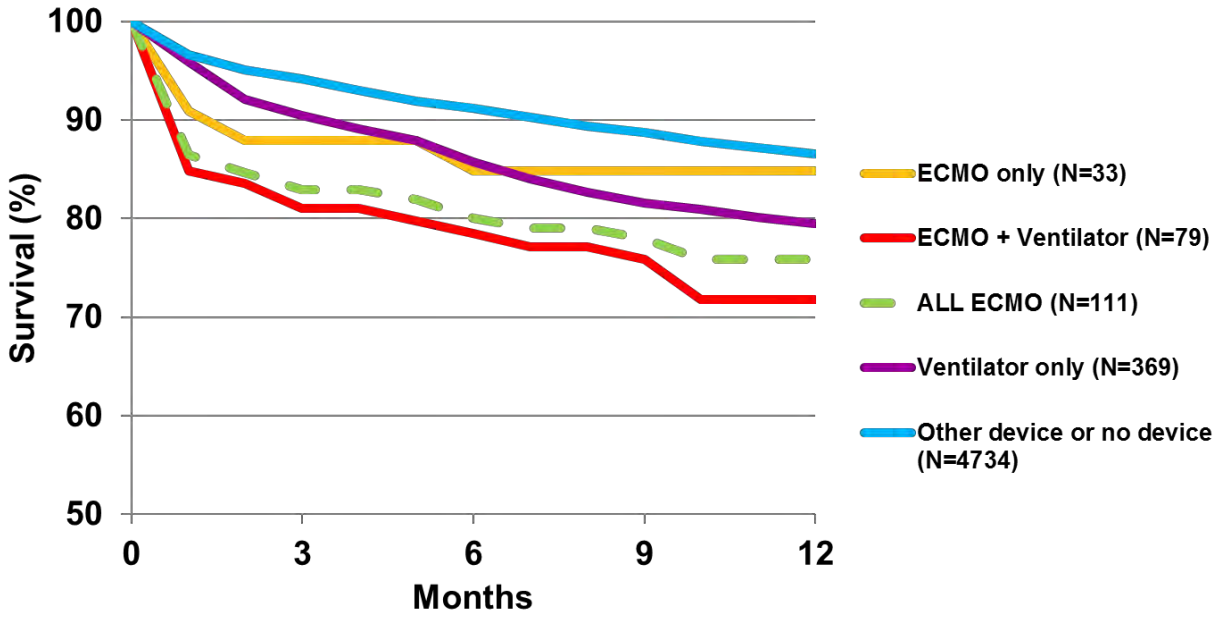


Figure 2: Post-Transplant Survival by Device

Single-center and multi-center retrospective studies have also examined the efficacy of bridging lung candidates to transplant with ECMO by examining post-transplant outcomes. Some found that one- and two-year survival rates are not adversely affected by pre-transplant ECMO use.[7] Others found use of ECMO as a bridge to transplant to be warranted, but found that "time on ECMO was a significant risk factor for death, either during the bridge or after transplant.[8]" As post-transplant survival is an important factor in the LAS calculation, it is necessary for the Lung Subcommittee to ensure that this aspect of the LAS is verified for candidates supported by ECMO.

Though the OPTN collects some relevant data, the Thoracic Committee determined that it is not sufficient to determine how ECMO should be incorporated into the LAS calculation, and therefore proposes collecting ECMO data on upon waitlist removal in UNet[SM].

Expected Impact on Living Donors or Living Donation:

No known impact on living donors or living donation.

Expected Impact on Specific Patient Populations:

No known impact to specific patient populations.

[7] Toyoda, Yoshiya, Bhama, J.K., Shigemura, N., Zaldonis, D., Pilewski, J., Crespo, M., and Bermudez, C. "Efficacy of extracorporeal membrane oxygenation as a bridge to lung transplantation." *The Journal of Thoracic and Cardiovascular Surgery*, 145:4 (2013): 1065-1071. Accessed August 11, 2014. DOI: 10.1016/j.jtcvs.2012.12.067.

[8] Crotti, Stefania, Iotti, G., Lissoni, A., Belliato, M., Zanierato, M. Chierichetti, M., Di Meo, G., Meloni, F., Pappalettera, M., Nosotti, M. Santambrogio, L., Vigano, M., Braschi, A. and Gattinoni, L. "Organ allocation waiting time during extracorporeal bridge to lung transplant affects outcomes." *Chest Journal.* 144(3)(2013):1018-1025. Accessed August 11, 2014. doi:10.1378/chest.12-114.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal furthers the OPTN Strategic Goal of improving survival for patients with end-stage organ failure by better matching donated organs to recipients by collecting data to fully understand the medical condition of candidates transplanted while supported by ECMO.

This proposal also furthers §121.8 of the Final Rule, which states: "(a) the Board of Directors…shall develop…policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies: (1) Shall be based on sound medical judgment; … (6) Shall be reviewed periodically and revised as appropriate". Collecting ECMO data will assist the Thoracic Committee in further refining the LAS based on objective medical evidence. It will also assist the Thoracic Committee in reviewing the LAS to ensure that it properly accounts for the medical condition of candidates supported by ECMO during their time on the waiting list.

Plan for Evaluating the Proposal:

The Thoracic Committee hypothesizes that more data regarding ECMO and ventilatory support will be submitted to the OPTN upon implementation of the modifications to the candidate removal page in Waitlist[SM]. The Committee further hypothesizes that the percentage of candidates supported by ECMO during their time on the waitlist will increase as ECMO continues to become a more common therapy for patients with end-stage lung disease.

The Thoracic Committee will review the additional data reported on the candidate removal page during its annual review of the LAS system. When the Committee agrees there are ample data to begin analysis and to model whether ECMO can be incorporated into the LAS calculation, the Lung Subcommittee will work with SRTR to complete this task.

Additional Data Collection:

As described in depth above, additional data collection will be required as a result of this proposal. This data collection effort is justified by the OPTN Principle of Data Collection: "Institutional members must provide sufficient data to OPTN to allow it to: a) Develop transplant, donation and allocation policies."

Expected Implementation Plan:

This proposal will require programming in UNet[SM] to edit the candidate removal page in Waitlist[SM] to add a section on mechanical ventilatory support.

Upon implementation, transplant programs will be required to provide the OPTN with data regarding all ventilatory devices used to support a candidate during his or her time one the waitlist. This information will be reported retrospectively, each time a candidate is removed from the waitlist. Transplant programs should become familiar with the new data fields so that the data are reported accurately.

Communication and Education Plan:

Upon Board approval, transplant professionals (specifically lung program personnel) will be informed about the upcoming requirement of submitting ECMO use information on the candidate removal page.

System notices will be sent to UNet[SM] users to provide advance notice of the change 30 days before implementation and again upon implementation, and a brief article about the implementation will be posted online. Any training will also be announced online. UNOS will develop educational materials in order to help transplant programs understand the new requirements.

The table below outlines the proposed communication and education activities.

Communication Activities			
Communication	Audience(s)	Deliver Method(s)	Timeframe
System Notice	UNet[SM] users	Through UNet[SM]	Upon implementation
Brief news items on the website and in the monthly e-newsletter.	Lung transplant centers	Online	Upon implementation

Compliance Monitoring:

This proposal will not affect monitoring of transplant hospitals.

Policy or Bylaw Proposal:

This section is not applicable because policy language is not affected by this proposal. However, the OPTN Principles of Data Collection require that “new data collection will require approval by the Policy Oversight Committee and the Board of Directors of the OPTN, and be subject to public comment.” Because this proposal requires additional data collection from OPTN members, it must be circulated for public comment.

At-a-Glance

- **Affected/Proposed Policies and Bylaws**
  Policy 1.2 Definitions; 2.2 OPO Responsibilities; 2.12.C Authorization Requirement; 5.2 Maximum Mismatched Antigens; 5.4.B Order of Allocation; 5.5.A Receiving and Reviewing Organ Offers; 5.5.B Time Limit for Acceptance; 5.9 Allocation of Other Organs (Elimination); 12.1 Waiting Time; 12.2 VCA Allocation; 14.6 Registration and Blood Type Verification of Living Donors before Donation; 18.1 Data Submission Requirements; 18.2 Timely Collection of Data; 18.3 Recording and Reporting the Outcomes of Organ Offers; OPTN Bylaws, Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs; Appendix D.2 Designated Transplant Program Requirement; OPTN Bylaws, Appendix J Membership Requirements for Vascularized Composite (VCA) Transplant Programs; Appendix K Transplant Program Inactivity, Withdrawal, and Termination; Appendix M Definitions

- **Vascularized Composite Allograft (VCA) Transplantation Committee**

  This proposal updates existing OPTN policy and bylaw language and establishes new requirements to add Vascularized Composite Allografts (VCAs) to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN). Specifically, it contains the following elements:

  1. Definition of a VCA
  2. VCA Membership Criteria
  3. VCA allocation
  4. Donor authorization to recover VCAs
  5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  In February, 2014, all U.S. OPOs responded to a survey given by AOPO asking to describe actual and planned VCA activity in their DSA. The survey found that 28 patients had received VCA transplants at 11 different transplant centers and that nine patients at six different transplant centers were awaiting transplant. As of August 29, 2014, there were 15 OPTN approved VCA transplant hospitals and seven VCA candidates registered on the OPTN waiting list.

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal meets five of the six goals outlined in the OPTN Strategic Plan:
  Goal 1: Increase the number of transplants
  Goal 2: Increase access to transplants
  Goal 3: Improve survival for patients
  Goal 4: Promote transplant patient safety
  Goal 6: Promote the efficient management of the OPTN

  Establishing a system for VCA transplantation addresses the key goals outlined above by:
  - Providing consistency and structure to VCA policies and programs.
  - Improving access to VCA transplantation for patients who might benefit by clarifying VCA donor authorization and related protocols.
  - Facilitating the development and exchange of information about candidate appropriateness for transplant, available VCA donors and candidates, and candidate prioritization.
  - Helping to maximize the number of VCAs recovered for transplant and promote the best use of donated organs.
  - Developing guidance for the evaluation and management of VCA candidates.
  - Addressing the changing field of transplantation by responding to a new area of organ allocation policy development.

Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)

Affected/Proposed Policy:
OPTN Policy 1.2 Definitions; 2.2 OPO Responsibilities; 2.12.C Authorization Requirement; 5.2 Maximum Mismatched Antigens; 5.4.B Order of Allocation; 5.5.A Receiving and Reviewing Organ Offers; 5.5.B Time Limit for Acceptance; 5.9 Allocation of Other Organs (Elimination); 12.1 Waiting Time; 12.2 VCA Allocation; 14.6 Registration and Blood Type Verification of Living Donors before Donation; 18.1 Data Submission Requirements; 18.2 Timely Collection of Data; 18.3 Recording and Reporting the Outcomes of Organ Offers; Appendix D Membership Requirements for Transplant Hospitals and Transplant Programs; Appendix D.2 Designated Transplant Program Requirement; Appendix J Membership Requirements for Vascularized Composite (VCA) Transplant Programs; Appendix K Transplant Program Inactivity, Withdrawal, and Termination; Appendix M Definitions

Vascularized Composite Allograft (VCA) Transplantation Committee

Public Comment Response Period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

This proposal updates existing OPTN policy and bylaw language and establishes new requirements to add Vascularized Composite Allografts (VCAs) to the definition of organs covered by the rules governing the operation of the Organ Procurement and Transplantation Network (OPTN). Specifically, it contains the following elements:

1. Definition of a VCA
2. VCA Membership Criteria
3. VCA allocation
4. Donor authorization to recover VCAs
5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

By statute, the Secretary of HHS may expand the definition of human organs and has exercised this authority by adding VCAs to the covered list of human organs under the OPTN modified Final Rule. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) to develop VCA policies prior to implementation of the modified Final Rule which became effective July 3, 2014. *Because of the pending statutory change at the time, these policy changes were approved by the OPTN Board of Directors during its June 23-24, 2014 meeting with a "sunset" date on September 1, 2015. The Board will review and consider these public comments for approval during the June 1-2, 2015 meeting.* More discussion within the VCA transplant community will be necessary to develop a refined system guiding OPTN, OPO, and transplant center processes for VCA transplantation.

The Bylaws and Policies contained within this proposals mirror those approved by the Board in June 2014. Concurrent with that effort, the VCA Committee began work on more long-term, substantive data collection policies. A separate proposal concerning those efforts is also being released during this public comment period. If comment is favorable on the separate data collection proposal, those provisions would be forwarded for final approval instead of the proposed amendments to Policies 18.1 and 18.2 in this proposal.

Background and Significance of the Proposal:

Vascularized Composite Allotransplantation i.e. “allografts” (VCA) refers to transplants composed of several different kinds of tissues (i.e., skin, muscle, bone), such as those in the hand, arm, or face, transferred from donor to recipient as a single functional unit.[1] This emerging field of transplantation has become a viable reconstructive option for patients with extensive tissue defects and severe dysfunction, often achieving functional and cosmetic outcomes not previously possible with existing techniques. Over the past decade, a rapidly growing number of face and upper extremity transplants have been performed worldwide with highly encouraging outcomes.[2] A number of OPTN member transplant hospitals are currently performing these types of procedures, necessitating oversight of this new area of transplantation.

On March 3, 2008, HRSA, a division of the Department of Health and Human Services (HHS), published a Request for Information (RFI) in the Federal Register requesting feedback from stakeholders and the public on whether VCAs should be included within the OPTN Final Rule's definition of organs. The RFI also sought input on whether VCAs should be added to the definition of human organs covered by section 301 of NOTA.

Based upon a review of VCA characteristics and submitted public comments, it was determined that VCAs should be included within the definition of organs covered by the OPTN Final Rule (42 CFR part 121) and section 301 of NOTA. On December 16, 2011, this intention was published in a notice of proposed rulemaking in the Federal Register. The addition of VCAs to the OPTN Final Rule's definition of organs, subjects VCA transplantation to the requirements of the OPTN Final Rule and OPTN oversight.

The OPTN was subsequently directed by HRSA to establish policies regarding VCA transplantation within its existing policy structure, with the goal of instituting a basic framework for VCA transplantation prior to implementation of the Final Rule modifications on July 3, 2014. Because of the pending statutory change at the time, these policy changes were approved by the OPTN Board of Directors during its June 23-24, 2014 meeting with a “sunset” date on September 1, 2015.

The OPTN Vascularized Composite Allograft (VCA) Transplantation Committee (Committee), comprising representation from U.S. transplant programs with experience in VCA transplantation and the major transplant and procurement societies, discussed and proposed policy and bylaw recommendations for the major areas identified for VCA program and allocation oversight. The Committee and subcommittees reviewed and discussed internal processes of transplant programs currently involved in VCA transplants. The Committee also examined the evolving body of literature surrounding VCA transplantation, to define the major issues involved with creating a temporary but workable structure for VCA programs.

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[1] Blake D. Murphy, Ronald M. Zuker, Gregory H. Borschel, "Vascularized composite allotransplantation: An update on medical and surgical progress and remaining challenges," *Journal of Plastic, Reconstructive, and Aesthetic Surgeons*, 66, no.11 (2013): 1449 http://www.ncbi.nlm.nih.gov/pubmed/23867239.

[2] Gerald Brandacher, “Composite tissue transplantation”, *Methods Mol Biol*. (2013); 1034: 103. doi: 10.1007/978-1-62703-493-7_5

A review of available literature shows that professional experience in VCA transplantation is progressing, with close to 150 procedures performed worldwide.[3] Outstanding results of more than a decade have been achieved with excellent short and long-term outcomes reported. Although functional outcomes have exceeded expectations, acute rejections are common in the early postoperative period with immunosuppression related side-effects often reported.[4] The risks of lifelong immunosuppression continue to be an important factor when evaluated against quality of life and functional benefits. OPTN oversight of this developing field will help provide the framework for an effective and balanced system, facilitating the collection of data for studying outcomes and best practices, and maximizing the benefit to patients and society.[5]

In preparation for VCA policy development efforts, the VCA Committee viewed the results of a survey of the Association of Organ Procurement Organizations (AOPO) to assess the number of hospitals currently transplanting VCAs, or planning to in the near future. The number of transplant programs involved in VCA transplantation is small, though interest in VCA transplantation is increasing. As of February 2014, the results of the survey showed:

- 28 VCA transplant recipients were transplanted at 11 different transplant centers.
    - 6 face transplants
    - 7 bilateral upper extremities
    - 14 unilateral upper extremities
    - 1 multiple VCA transplant – a face and a bilateral upper extremity.
- 9 patients at 6 different transplant centers were waiting for a VCA transplant
    - 4 awaiting a face transplant
    - 4 awaiting a bilateral upper extremity transplant
    - 1 awaiting a unilateral upper extremity transplant.

There are an additional nine transplant hospitals in the planning stages for a new VCA transplant program, with a few close to approving patients, including one children's hospital.

Although the VCA field is emergent and literature examining outcomes is still evolving, incorporation of these procedures within the authority of NOTA and the Final Rule is evidence of its significance to the field of transplantation. More data is needed to investigate immunologic issues and characteristics of VCA unique to face vs. hand transplantation. As the field advances, this additional evidence will help guide future policy decisions.

[3] Diaz-Siso JR, Bueno EM, Sisk GC, Marty FM, Pomahac B, Tullius SG."Vascularized composite tissue allotransplantation--state of the art", *Clin Transplant*. (2013) May-Jun; 27(3): 330. Epub 2013 Apr 14.

[4] Kaufman CL, Ouseph R, Marvin MR, Manon-Matos Y, Blair B, Kutz JE.. "Monitoring and long-term outcomes in vascularized composite allotransplantation," *Curr Opin Organ Transplan.* (2013): 652, http://www.ncbi.nlm.nih.gov/pubmed/24220047

[5] Cendales, LC, Rahmel, A, Pruett, TL, "Allocation of vascularized composite allografts: what is it?" *Transplantation*, (2012): 1086. doi: 10.1097/TP.0b013e31824b073f.

Supporting Evidence and/or Modeling:

This proposal establishes minimum requirements for OPTN transplant programs that perform VCA transplantation. Specifically, it contains the following elements:

1. Definition of a VCA
2. VCA Membership Criteria
3. VCA allocation
4. Donor authorization to recover VCAs
5. Policy and bylaw language necessary to specifically exempt application to VCAs and avoid eliminating existing safeguards that apply to all other organs.

Definition of a VCA

The final rule modifications require the OPTN to "identify all covered body parts in any policies specific to vascularized composite allografts, defined in §121.2,[6]" so that VCAs are able to be clearly distinguished as organs under the OPTN policy framework. On February 25, 2014, the VCA Committee convened in Chicago Illinois to discuss VCA topics, including a definition of covered VCA parts. The VCA Committee first needed to confirm that VCAs were covered under the purview of HRSA under the final rule and not the Food and Drug Administration (FDA), as the definition of a VCA contains components previously regulated by the FDA. Based upon their clinical characteristics, the HHS has determined that VCAs are more characteristic of organs as defined specifically in NOTA and subject to regulation consistent with organ transplantation. The Committee discussed distinguishing factors between cellular and tissue-based products regulated by the FDA and those components under the purview of the OPTN, since a body part would be excluded from the coverage of FDA regulations once it is defined as an organ under the OPTN final rule. The OPTN modified final rule includes nine criteria that must be met in entirety for a body part to be defined as a VCA.

The nine criteria for VCAs are:

1) That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2) Containing multiple tissue types;
3) Recovered from a human donor as an anatomical/structural unit;
4) Transplanted into a human recipient as an anatomical/structural unit;
5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
6) For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7) Not combined with another article such as a device;
8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

The Committee reviewed and discussed the nine criteria. An initial concern was expressed with regard to criterion 7 which refers to "a device" that in combination with another article would change its classification as a VCA organ. No specific examples were recognized that would

[6] OPTN Final Rule 42 CFR 121.2 - Definitions

pertain to face and limb transplants; however, the Committee discussed the possibility of future advancements in technology and medicine that could eventually incorporate a mechanical device within a composite, causing a change in its definition. The Committee requested that HRSA contact the FDA to obtain clarity on criterion #7.

The Committee also discussed other body parts that could be incorporated into the definition of a VCA transplant in the future. Upper extremity (most notably hands) and face transplants are the most frequently performed VCA transplant procedures in the U.S. and are the subject of extensive ongoing clinical research programs. Under the modified final rule, any OPTN policy that applies broadly to solid organs would apply to all body parts meeting the definition for VCAs unless otherwise specified. Therefore, other VCA procedures meeting the nine criteria to define a body part as a VCA, would also be subject to general OPTN policies. See Fig 1 below.

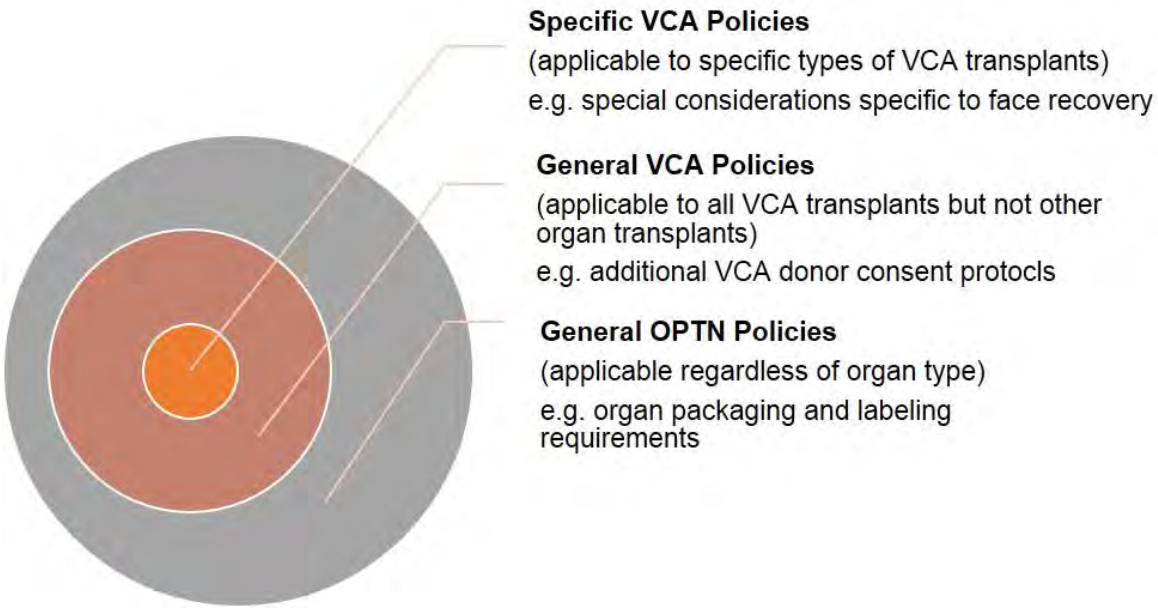

Figure 1: Tiers of OPTN Policy as applicable to VCA transplants.

For the initial phase of policy development, OPTN VCA policies will focus on upper extremity and face transplants. As the field advances, specific body parts may be added to the list of VCA organs with subsequent development of new policies.

During its conference call meeting on March 25, 2014, the VCA Committee was updated with the requested clarification from HRSA regarding criterion 7. The Committee was advised that the FDA would determine if there has been a material change to the device which could impact the safety, effectiveness, purpose, or use of that device. As long as the VCA and any devices used during the procedure are not changed for an unintended purpose, the transplant would remain under the oversight of the OPTN. As the concerns raised by criterion 7 seemed to be outside of the intention of adding the nine criteria to the OPTN final rule, the Committee confirmed its intent to adopt the nine criteria as written, with public comment feedback offering the potential for more interpretive, clarifying language in the future.

During its March 29, 2014 meeting, the Committee unanimously supported (16 approve, 0 oppose, 0 abstain) a motion to submit the proposed OPTN policy language for the Board of Director's consideration at its June 23-24, 2014 meeting. No further changes were made to the approved policy language during subsequent committee or Board discussions.

Final approved policy language is included at the end of this proposal.

VCA Membership Criteria

As the OPTN Contractor, UNOS is a membership organization which is required under NOTA to establish membership and medical criteria for allocating organs. The OPTN Bylaws contain numerous membership requirements that must be in place at the transplant hospital, and approved by the Membership and Professional Standards Committee (MPSC), before the hospital may be involved with transplantation. As such, basic bylaw language would need to be in place to accommodate OPTN membership for VCA programs in preparation for the July 3, 2014 modified final rule implementation date. Future VCA membership bylaws will address care, provider, and infrastructure requirements.

During its meeting on February 25, 2014, the VCA Committee reviewed draft bylaw language and a list of necessary elements for a VCA program prepared by the American Society of Transplant Surgeons (ASTS) VCA Committee, to establish the basic membership requirements for VCA programs that will be sent for the Board's consideration in June.[7] The limited number of VCA transplants performed to date prevented comparison of current membership requirements for other organ-specific programs against VCA membership requirements. Therefore, the Committee was cautioned against developing overly specific language for personnel for whom no requirements or comparison currently exists. The Committee discussed core membership requirements for VCA programs. A reconstructive surgical director and medical director were suggested as identified responsible VCA program staff in an attempt to simulate the primary surgeon/surgical director and primary physician/medical director bylaw structure. The Committee also supported the use of a letter template referenced in the proposed bylaws language that would obtain all necessary VCA transplant program information in place of a formal membership application.

The required timing for member notification to the OPTN of its intention to perform VCA transplants was discussed. The Committee considered including the time that a potential VCA recipient is identified and the time a candidate is considered "listed," but ultimately decided against both because adding VCA candidates to a waiting list on UNet^{SM} will not be immediately feasible. The Committee determined that other preparations, including preliminary screening of patients, were more indicative of program intent, and added language requiring that a transplant hospital notify the OPTN Contractor once it has patients "ready to undergo screening for a VCA transplant." The requirement for a VCA program to be at a transplant hospital that is a "member in good standing" was also added, as well as a recommendation to require a letter from the program's local OPO, attesting to its interaction with the potential VCA program about the necessary coordination of logistics, etc. of establishing a program. Requiring this exchange with the local OPO would demonstrate that a program has begun the necessary planning to perform VCA transplants.

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Following review of the initial requirements, the Committee unanimously supported the draft language and recommended that a VCA Membership Subcommittee be created to review the draft language for additional core membership requirements.

On March 25, 2014, the VCA Membership Subcommittee met by teleconference call to discuss additional edits to the bylaw language suggested by UNOS staff. The edits included eliminating the requirement that the program be a "member in good standing" and presentation of two options for clarifying whether the VCA transplant hospital must have another approved transplant program in operation to *receive and maintain* VCA transplant program approval. UNOS staff noted that the terms "member in good standing" and "member not in good standing" are not defined in the OPTN/UNOS Bylaws and the process to define these terms would require additional input from numerous stakeholders, which would be outside of the scope of the VCA membership requirements. The subcommittee also discussed whether the VCA program would be able to maintain program approval if the approved transplant program were to close. Committee members expressed that the transplant hospital must have another functioning transplant program, since the VCA program would rely on that program's transplant expertise. Additionally, it would be advantageous for new VCA programs to align with the organization and structure required of OPTN approved transplant hospitals. The Committee agreed to amend the bylaw language removing the term "member in good standing and adding language requiring a hospital to have another approved transplant program in addition to the VCA program, in order to receive and maintain VCA transplant program approval.

The subcommittee also discussed the recommendation for the transplant hospital to contact the OPTN about the establishment of a VCA program when it "has a candidate ready to undergo screening for a VCA transplant." UNOS staff expressed concern that the language was not well defined for compliance monitoring purposes. The Committee recommended modifying the language to state that a transplant hospital must contact the OPTN upon its commitment to perform VCA transplants. The Committee unanimously supported the amended bylaw language.

On April 22, 2014, the VCA Membership Subcommittee met again to determine if additional requirements should be added to the proposed bylaws. The subcommittee agreed that three positions (chief administrative office for the institution, a reconstructive surgeon, and a transplant specialist), all with specific named expertise, should be designated as responsible VCA transplant program personnel and required to sign the letter of intent which would serve as the application for a VCA program.

During its conference call on April 29, 2014, the VCA Committee approved additional bylaw language recommended by UNOS staff, specifying that the letter of notification also include the contact information and signatures of each of the three named VCA program personnel.

The Committee approved (For – 11, Against – 0, Abstention – 0) the amended bylaw language detailing basic Membership Requirements for VCA Transplant Program, for the Board of Director's consideration at its June 2014 meeting. An amendment to the proposed bylaw language was made at the Board meeting to correct discrepant language that appeared in the Board book.

Final approved bylaw language included at the end of this proposal.

Subsequent to the Board meeting, Committee leadership discussed and agreed that the proposal should not give a transplant hospital "blanket" approval to perform transplants of <u>any</u> VCA graft. The language was drafted to avoid burdensome restrictions on those VCA programs that were operating at the time of the Final Rule amendment. Future membership requirements will outline

criteria for VCA-specific transplant programs (upper limb, face, abdominal wall, etc…). A subcommittee of the VCA Committee has begun work on this effort.

VCA Allocation

Leading into the June, 2014 Board meeting were two efforts related to VCA Allocation:

- Elimination of Policy 5.9 (Allocation of Other Organs)
- Creation of a new policy regarding VCA allocation

OPTN Policy 5.9 (Allocation of Other Organs) addresses the "allocation of other organs not specifically addressed in other policies." Prior to June 2014, the allocation of all organs were addressed in policy but when the OPTN began oversight of VCA transplants on July 3, 2014, there would have been an opportunity for confusion if OPOs tried to allocate organs using this outdated policy. This policy is outdated and contains a point system for medical urgency and distance from the transplant center that has never been programmed. Therefore, the OPO Committee voted unanimously to rescind this policy and submit the recommendation to the Board of Directors during its June 22-23, 2014 meeting. The Board agreed to eliminate Policy 5.9.

The VCA Committee was asked to develop a temporary mechanism for allocation of VCAs in preparation for implementation of the OPTN modified Final Rule. The temporary mechanism will remain in place until the Committee can develop a more robust allocation scheme that will be programmed. During its teleconference call on March 25th, the VCA Committee initially considered referencing ongoing VCA allocation policy development as an intermediate solution, to avoid unintended consequences resulting from an overly simplified policy, and allow more thorough deliberation of allocation concepts. As the VCA community is anxiously awaiting direction from the OPTN on allocation, it was determined that this guidance was needed prior to implementation of the modified Final Rule, to assist transplant programs in their decision making. The general principles of allocation outlined in NOTA and approved by the Board were used to help guide VCA allocation decisions.

The VCA Committee discussed factors that could be considered in a simple allocation policy for VCA organs, to help define candidate priority when multiple recipients are waiting and clinically eligible for a transplant. Currently, the small number of VCA patients waiting at transplant programs allows for individualized allocation arrangements with OPOs. Eventually, as program participation is expanded, rank ordering candidates with similar characteristics will require a more consistent, defensible, and methodical approach. Waiting time within the organ procurement organization's donation service area was suggested. Although basic, it prevents the perception of unfair organ allocation and would be a reasonable first step until more refined allocation policies can be developed. The Committee recommended that a working group of VCA Committee members develop draft policy language based on allocation practices used by existing VCA programs, for presentation to the Committee during its next teleconference call.

The VCA Committee met on May 9, 2014, to review several options for a general allocation scheme for VCA transplantation. The backdrop for the effort included the stated allocation principle of increasing access of recipients to suitable donors, while safely and appropriately promoting experience in the field. As the current setting for VCA transplantation is starkly contrasted with that of traditional solid organ transplantation where organ demand exceeds supply, the goal would be to prevent the exclusion of suitable donors, due to policy requirements that are overly restrictive.

The VCA Committee viewed draft policy language presenting three options for allocating VCAs, each with a proposed definition of waiting time. It was noted generally that the use of waiting time as a basic determinant of allocation priority, is controversial and considered to be inequitable in deceased donor allocation. If used for VCA allocation, impacts to candidates should be carefully studied. The Committee discussed revisions to the waiting time language. The Committee wanted a method to sort candidates who will have been waiting for a VCA transplant when the Final Rule amendment and OPTN oversight goes into effect. The Committee also deliberated between language indicating that waiting time will begin when an OPO actively seeks a donor for either an identified potential VCA "recipient" or "candidate." It was noted that a "recipient" and "candidate" are defined in OPTN policy as a patient who has already received a transplant or a patient who is currently on the OPTN waiting list. Members articulated that the term "candidate" establishes that the patient has not yet been transplanted and agreed that it was the most appropriate term. The draft policy language was amended to reflect that waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.

The proposed allocation options were summarized and discussed. The first option would allocate VCAs by compatible blood types and physical characteristics, distinguishing allocation of limbs by bilateral or unilateral transplants, then prioritizing according to level of HLA mismatch and candidate sensitization. The second option would allocate VCAs to candidates with compatible blood types and similar physical characteristics, prioritizing according to geography with allocation first to regional and then national candidates. The third option would allocate VCAs according to geography and level of HLA mismatch with the donor, prioritizing first local ABO identical and compatible candidates, then regional ABO identical and compatible candidates, followed by national ABO identical and compatible candidates.

The Committee debated the appropriateness of allocating VCAs based upon the underlying allocation concepts represented by the options, including degree of HLA mismatch, candidate sensitization, geography, and type/number of VCA procedures. Ethically, prioritization for a scarce resource should allow identical transplants to precede compatible transplants. However, as organ scarcity may not be established within the interim policy timeframe, prioritization based on broad HLA compatibility would be supported if impacts on blood type O recipients are carefully monitored. Additionally, prioritizing zero mismatched candidates under an interim policy could be burdensome to transplant programs and would likely only apply under very rare circumstances. Prioritization based upon candidate sensitization could be helpful for some patients, but data supporting a specific sensitization threshold for patients is currently unavailable.

In discussions regarding the use of geographic boundaries for prioritization, members delivered strong ethical arguments against the practice of using OPO boundaries as the first layer of allocation or using historical, regional boundaries, suggesting that these approaches are reliant on an outdated allocation model. The Committee also referenced the lack of data on the amount of cold ischemic time that would negatively impact VCAs. However, members agreed that if geography is used in VCA allocation, regional distribution would be the most acceptable of the methods that could be implemented in July, noting that many transplant programs will not have an active VCA program during the interim policy period.

Finally, the Committee considered candidate prioritization based upon VCA type, functionality, and number of procedures needed by a candidate. Various objectives were deliberated, including the need for two upper extremity procedures as compared to one, avoiding multiple surgeries, and matching candidate and donor characteristics. Ultimately, the Committee chose not to give priority to candidates based on the type or number of VCAs required.

Acknowledging the numerous complexities involved with determining individual candidate priority for VCAs, and recognizing that benefits from a temporary may not be demonstrated during the interim policy period, the VCA Committee ultimately chose an option that provided the most broadly defined allocation. The option selected would allow decisions to be individualized for matching an organ to a specific patient, with processes operationalized by the transplant program. The option also circumvents application of concepts used in solid organ transplantation to VCA transplantation, when they may not be the best fit.

Because this system will not be programmed in UNet^{SM} during the interim policy period, the manual VCA matching process was loosely outlined for the Committee:

- Transplant programs will register their VCA candidates in a document that they will securely transmit to UNOS.
- UNOS will compile all of the candidate registrations into a master list which would be distributed to OPOs.
- OPOs will match VCA donors to candidates using the master list.
- In the event an OPO identifies a VCA donor that is suitable for more than one candidate from the master list, allocation will first be offered to regional candidates.
- If the organ is not accepted regionally, allocation will be offered to national candidates.
- Within each classification, waiting time will be used as the tie breaker between candidates.

The VCA Committee approved the proposed policy language regarding VCA Allocation for the OPTN/UNOS Board of Directors consideration at the June 23-25, 2014 meeting (Yes – 14, No – 0, Abstentions – 0).

Final approved policy language is included at the end of this briefing paper.

While not directly related to VCA allocation, it is worth noting that the Secretary of Health and Human Services responded to the possibility of a living VCA donor in the amendment to the OPTN Final Rule. The Secretary affirmed that oversight of living donors was under the auspices of the OPTN. The definition of a VCA in both the OPTN Policies and Bylaws was adopted from the Final Rule. This Final Rule definition intentionally did not prohibit the possibility of living VCA donors. Cases of live VCA donations have been reported in Europe[8], however there are no candidates for living VCA donors registered with the OPTN. The Committee felt it was prudent to not set restrictive policy language in this evolving clinical area. As the field of VCA transplantation evolves, the VCA and Living Donor Committees will review the implications of living donation in the context of VCA. This may translate into guidance or policy language.

Authorization Requirements for VCA Donation

During its February 25th meeting, the VCA Committee reviewed draft policy language to discuss the necessary elements that should be included in a VCA donor authorization process. Addressing public comment concerns, the Committee debated whether OPOs would need to obtain authorization to recover VCAs separately from the authorization to recover other organs for transplant. As a general rule, each OPO that is currently recovering VCAs has developed separate deceased donor authorization forms for potential VCA donors that extends beyond the

[8] Brannstrom, M., Johannesson, L., Gabel, M., Kvarnstrom, N., Tzakis, A., Olausson, M. "The First Clinical Trial of Uterus Transplantation: Surgical Technique and Outcome*", American Journal of Transplantation,* (2014): 44, http://onlinelibrary.wiley.com/doi/10.1111/ajt.12877/pdf

traditional authorization processes for potential whole organ donors. Separate authorization is necessary to maintain public trust and transparency with regard to this sensitive subject.

There was strong support among the Committee that OPTN policy should address potential concerns from the public about individuals who have previously registered to be organ donors but likely did not consider the possibility of VCAs. Authorization to recover organs is typically governed by state law following the Uniform Anatomical Gift Act (UAGA). Although state law dictates donor authorization, the OPTN is responsible for maintaining public trust in the nation's organ allocation system. A separate VCA donor authorization policy would not necessarily conflict with state law and the language may help states develop regulations specific to VCA donor authorization. The Committee agreed that distinguishing VCA authorization in policy would be important to establish public trust and not hinder life-saving organ transplantation. After debating specific terminology that would capture the expressed concerns, the Committee suggested adding the word "distinctly" to the proposed bylaws language. In the future, once VCA transplantation is more common, the Committee will consider whether that separate authorization is still necessary. The Committee agreed that the proposed policy language addressed potential concerns from the public by sending a message that VCAs will not be recovered unless agreed to by the persons responsible for making the donation decision and voted to support the proposed draft language.

During its April 29th conference call, the VCA Committee considered additional changes to the proposed policy language on VCA authorization approved during the February 25th meeting. The proposed changes were recommended by the chair of the Ethics Committee to be consistent with state law and clarify how VCA authorization is obtained. The language proposed by the Committee appeared to only allow surrogate consent for VCA donation in the setting of legally valid donor wishes. However, this requirement is in conflict with state gift law and many donor registries, as well as the UAGA. The majority of authorization for deceased donation is obtained from a general intent registry such as the Department of Motor Vehicles (DMV) driver license renewals, which does not distinguish between organs, tissue, or VCA. Authorization for VCA is not applicable to a general intent registry, since the donor's intent to donate VCA organs is not assumed. However, under the UAGA, authorization for a general deceased donation gift would not limit authorization for an additional specific VCA gift. Therefore, authorization for the specific VCA gift can originate from *either* the donor himself or a (surrogate) donation decision maker after the donor's death.

As policy language is not intended to include prescriptive elements of the donor consent process, the Committee also identified the need to reinforce the concept of separate consent with appropriate support and educational materials that would be non-binding to members. This guidance on VCA authorization was provided to the Board as supporting materials. Several committees and interested organizations are currently reviewing the guidance. If their reviews are favorable, it will be submitted as a guidance document to the OPTN Board of Directors.

The Committee agreed that the amended language promotes consistency with the law and current donor registries, and preserved the Committee's intent for a separate consent form and conversation about VCA donation.

The Committee approved the amended policy language detailing Authorization Requirements for VCA Donation for the OPTN/UNOS Board of Directors consideration at the June 23-25, 2014 meeting (For – 11, Against – 0, Abstention – 1)

Final approved policy language included at the end of this briefing paper.

Other Policy and Bylaw Modifications Specifically Exempting VCAs

In preparation for implementation of the modified Final Rule, UNOS staff researched requirements necessary for operationalizing VCA policies within the OPTN. The investigation included a comprehensive review of OPTN policies and bylaws and related UNet[SM] computer systems. It was determined that there were numerous sections of OPTN policy and the bylaws that would need to be amended to prevent application to VCAs and several computer systems that would need to be updated. Many OPTN/UNOS policies are not organ specific and would apply to VCAs unless specifically exempted. Additionally, several OPTN/UNOS computer systems are organ specific and would require programming updates to incorporate VCA policies. Although efforts are underway within UNOS to update these systems, the changes would not be in place by July. Therefore, electronic workaround solutions were developed to facilitate the interim policy and boilerplate policy language was proposed for specific sections of OPTN policy and the bylaws to ensure that all of the policies applicable to VCAs could be implemented and that existing safeguards for solid organs could be preserved. The proposed changes were approved by the Board in June 23-24, and will expire as solutions can be implemented.

The VCA Committee approved without edits, all proposed changes to several OPTN policies and bylaws that would be affected by addition of OPTN Policy 12.0, Vascularized Composite Allografts for the OPTN/UNOS Board of Directors consideration at the June 23-25, 2014 meeting (Yes – 14, No – 0, Abstentions – 0).

Final approved policy and bylaw language is included at the end of this briefing paper.

Expected Impact on Living Donors or Living Donation:

Portions of this proposal apply to living donors and portions of this policy are specific to deceased donation.

Definition of Organ

The change of the definition of organ in the Final Rule was not specific to deceased or living donation; it therefore applies to both deceased and living donation. This Final Rule definition intentionally did not prohibit the possibility of living VCA donors. Cases of live VCA donations have been reported in Europe[9]; however, there are no candidates for living VCA donors registered with the OPTN at this time. The application of this change to living donation was specifically addressed in the supplementary information to the Final Rule amendment.[10]

> *Comment*: One commenter questions how the VCA transplant waiting list will be categorized (i.e., by gender or race) and whether the OPTN will allow live donations or only recover a hand or face from someone who is about to die.
> *Response*: VCAs meet the definition of organs based on this rule and are no different from any other organs previously listed under NOTA and the OPTN final rule. Each transplant center has its own selection criteria for accepting potential candidates for VCA transplant and placing them on the waiting list. The OPTN final rule provides specific allocation performance goals (42 CFR 121.8(b)), including: "Standardizing the criteria for determining

[9] Brannstrom, M., Johannesson, L., Gabel, M., Kvarnstrom, N., Tzakis, A., Olausson, M. "The First Clinical Trial of Uterus Transplantation: Surgical Technique and Outcome*", American Journal of Transplantation*, (2014): 44, http://onlinelibrary.wiley.com/doi/10.1111/ajt.12877/pdf

[10] *See* 78 FR 40033 available at https://www.federalregister.gov/articles/2013/07/03/2013-15731/organ-procurement-and-transplantation-network.

suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists." The demographic categories mentioned by the commenter are not criteria utilized for placement on the organ wait list.

Live donor organs are addressed by OPTN policies. The most common are kidney and liver. Although a potential living donor may express a desire to donate a VCA, no transplant center currently provides this service. Organs are not procured in the U.S. from any person "who is about to die," but in fact are obtained either willingly from a living donor or from a person who is already dead (deceased donor) with proper authorization.

Membership

The membership criteria for VCA programs is not specific to deceased or living donation; they apply to both. Therefore, a transplant program could apply to perform living donor VCA transplants.

Allocation of VCAs

The allocation changes in this proposal (elimination of Policy 5.9 (Allocation of Other Organs) and the creation of Policy 12 (Allocation of Vascularized Composite Allografts)) are both specific to deceased donors.

Donor Authorization

Subsequent to Board approval of the interim policies, a question was raised regarding the scope of the changes in Policy 2.12.C regarding the recovery of VCAs for transplant. Committee leadership has clarified that these are meant to be specific to deceased donors and expects the Committee to approve clarifying language in post-public comment. This is consistent with the structure of the current policy, which is a subsection of Policy 2 (Deceased Donor Organ Procurement).

Implementation Exemptions

As mentioned above, some sections of policy were exempted for VCAs due to logistical limitations within the timeframes required to implement this regulatory change. Exemptions in Policies 14.6 and 18.1 impact living donor transplants. These policy requirements will be restored as programming is put into place. Additionally, there will likely be new policies needed regarding living donors and VCAs. Those policy changes will be in future policy proposals.

Expected Impact on Specific Patient Populations:

In February, 2014, all U.S. OPOs responded to a survey given by AOPO asking to describe actual and planned VCA activity in their DSA. The survey found that 28 patients had received VCA transplants at 11 different transplant centers and that nine patients at six different transplant centers were awaiting transplant. As of August 29, 2014, there were 15 OPTN approved VCA transplant hospitals and seven VCA candidates registered on the OPTN waiting list.

Expected Impact on OPTN Strategic Plan and Adherence to OPTN Final Rule:

This proposal meets five of the six goals outlined in the OPTN Strategic Plan:

Goal 1: Increase the number of transplants
Goal 2: Increase access to transplants
Goal 3: Improve survival for patients
Goal 4: Promote transplant patient safety
Goal 6: Promote the efficient management of the OPTN

Establishing a system for VCA transplantation addresses the key goals outlined above by:

- Providing consistency and structure to VCA policies and programs.
- Improving access to VCA transplantation for patients who might benefit by clarifying VCA donor authorization and related protocols.
- Facilitating the development and exchange of information about candidate appropriateness for transplant, available VCA donors and candidates, and candidate prioritization.
- Helping to maximize the number of VCAs recovered for transplant and promote the best use of donated organs.
- Developing guidance for the evaluation and management of VCA candidates.
- Addressing the changing field of transplantation by responding to a new area of organ allocation policy development.

Plan for Evaluating the Proposal:

The following data will be monitored:

- The number of VCA candidates and transplants by region, by center, and by basic demographics (e.g., VCA organ type, age, gender, ethnicity, ABO blood group, CPRA)
- Reasons for bypass or refusal of VCA organ offers

Additional Data Collection:

Additional data collection is required as a result of this proposal. At this time, donor and potential recipient matching through DonorNet® is not available for VCA organs and will require significant programing changes in the future. In the meantime, an interim solution has been developed. The following worksheets must be submitted by approved VCA transplant programs in order to register VCA candidates on the OPTN waiting list and remove the candidates from the list:

- Contact information for transplant program staff to receive organ offers (**Exhibit A**)
- Candidate registration (**Exhibit B**)
- Candidate removal (**Exhibit C**)

A spreadsheet of VCA candidates is maintained by OPTN and is updated when VCA candidates are added or removed.

Expected Implementation Plan:

The proposed policy and bylaw modifications were effective upon implementation of the modified Final Rule on July 3, 2014. The changes were proposed with a "sunset" date and will expire on September 1, 2015.

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would lift the subset clause on the bylaws and policies already in place – thereby making them permanent bylaws and policies.

Communication and Education Plan:

The VCA Committee advised that a comprehensive educational plan, as well as timely communication and notice to members and the public, will be critical to prevent misconceptions about VCA donor authorization and any application to deceased donor transplantation. A resource document for OPTN members, differentiating VCA donor authorization from authorization for other organs donation, has been developed for usage during the interim policy development period. This resource document was distributed to the OPO community in advance of the July 3, 2014 transition date. Immediate educational and instructional efforts will address the new VCA requirements, with ongoing support and instruction provided to members as the VCA policy framework is developed and refined.

Information about the new requirements also will be incorporated into the OPTN Evaluation Plan and addressed in the context of ongoing member notification as the plan is periodically updated. In addition, notification of the amended policy requirements would be included in the following routine communication vehicles:

- Policy notices
- System notices
- Member e-newsletter/blog articles
- Public Comment webinars

Compliance Monitoring:

This proposal would make permanent the temporary VCA policy structure which will be used for the 18 month interim policy period. The proposed language will not add new routine monitoring of OPTN members. Any data entered in UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested. Additionally, UNOS Membership staff and reviewers from the OPTN/UNOS Membership and Professional Standards (MPSC) Committee will review VCA transplant program application letters to ensure minimum program requirements are met prior to approval.

Policy or Bylaw Proposal:

OPTN Bylaws Appendix D: Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.
The following provisions of Appendix D do not apply to VCA transplant programs:

- *D.4: Transplant Program Director*
- *D.5: Transplant Program Key Personnel*
- *D.6: Changes in Key Transplant Program Personnel*
- *D.9: Review of Transplant Program Functional Activity*
- *D.10 A: Transplant Program Survival Rates*
- *D.10 B: Patient Notification Requirements for Waiting List Inactivation*
- *D.10 G: Relocation of Transfer of Designated Transplant Programs.*

D.2 Designated Transplant Program Requirement
In order to receive organs for transplantation, a transplant hospital member must have current approval as a designated transplant program for at least one organ. Designated transplant programs must meet at least *one* of the following requirements:

- Have approval as a transplant program by the Secretary of the U.S. Department of Health and Human Services (HSS) for reimbursement under Medicare.
- Have approval as a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.
- Qualify as a designated transplant program according to the membership requirements of these Bylaws.

The OPTN does not grant designated transplant program approval for any type of vascularized organ transplantation for which the OPTN has not established specific criteria. In order to perform vascularized organ transplantation procedures for which there are no OPTN-established criteria, including multi-visceral transplants, a hospital must be a transplant hospital member and have current approval as a designated transplant program ~~for at least one of the organ types involved in multi-visceral transplant~~. In the case of abdominal multi-visceral organ transplants, the transplant hospital must have approval as a designated liver transplant program. In the case of vascularized composite allografts (including, but not limited to, faces and upper extremities), the transplant hospital must have approval for at least one designated transplant program in addition to the vascularized composite allograft program designation.

APPENDIX J: ~~RESERVED~~ Membership Requirements for Vascularized Composite Allograft (VCA) Transplant Programs
This appendix describes the documentation transplant hospitals must provide when requesting approval as a designated VCA transplant program. VCAs include, but are not limited to, faces and upper extremities.

J.1 Letter of Notification
If a transplant hospital member commits to performing VCA transplants the hospital must send written notification of this intent to the OPTN Contractor. The notification to the OPTN Contractor

must include a written assurance from the local OPO that it will provide organs for use in vascularized composite allografts.

The letter of notification from the transplant hospital must be signed by *all* of the following individuals:

1. The chief administrative officer for the institution
2. A reconstructive surgeon with expertise in microsurgical reconstruction, prior experience in VCA, or in lieu of actual VCA experience, extensive experience in the applicable reconstructive procedure as required, such as hand replantation or facial reconstruction
3. A transplant physician or transplant surgeon at an approved transplant program that has completed an approved transplant fellowship, or qualifies by documented transplant experience, in a medical or surgical specialty.

The OPTN Contractor will then notify the transplant hospital member of the program designation

Bylaws Appendix K: Transplant Program Inactivity, Withdrawal, and Termination
This appendix defines transplant program inactivity, withdrawal, and termination, and outlines what members must do to be in compliance with OPTN obligations during these periods.
The following provisions of Appendix D do not apply to VCA transplant programs:

- *K.1: Transplant Program Inactivity*
- *K.2: Short-term Inactive Transplant Program Status*
- *K.3: Long-term Inactive Transplant Program Status.*

Appendix M: Definitions

D

Designated Transplant Program
An organ-specific program that has been approved by the MPSC to as part of the transplant hospital membership. A transplant hospital member may have transplant programs for transplantation of hearts, lungs, liver, kidneys, pancreas, pancreas islets, ~~and~~ intestines, and vascularized composite allografts. In order to be a transplant hospital member, the transplant hospital must have current designated transplant program approval for at least one organ. A designated transplant program may also be called a transplant program in these Bylaws.

O

Organ
~~*Organ* means a~~ A human kidney, liver, heart, lung, pancreas, ~~or~~ intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract)___ _____ Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled "For use in organ transplantation only."

V

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

1. That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2. Containing multiple tissue types;
3. Recovered from a human donor as an anatomical/structural unit;
4. Transplanted into a human recipient as an anatomical/structural unit;
5. Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
6. For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7. Not combined with another article such as a device;
8. Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
9. Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

Policy 1.2 Definitions

O

Organ

Organ allocation policies

OPTN Policies: *Policy 6: Allocation of Hearts and Heart-Lungs, Policy 7: Allocation of Intestines, Policy 8: Allocation of Kidneys, Policy 9: Allocation of Livers and Liver-Intestines, Policy 10: Allocation of Lungs, ~~and~~ Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets, and Policy 12: Allocation of Vascularized Composite Allografts.*

V

Vascularized Composite Allograft (VCA)

A transplant involving any body parts that meet *all* nine of the following criteria:

1) That is vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
2) Containing multiple tissue types;
3) Recovered from a human donor as an anatomical/structural unit;
4) Transplanted into a human recipient as an anatomical/structural unit;

5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
6) For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
7) Not combined with another article such as a device;
8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; and
9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.

W

Waiting list
A~~The~~ computerized list of candidates who are waiting to be matched with specific deceased donor organs for transplant.

2.2 OPO Responsibilities
The host OPO is responsible for all of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation. The previous sentence does not apply to VCA transplants; instead, members must allocate VCAs according to Policy 12.2: VCA Allocation.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage.
15. Maintaining a serum sample for each deceased donor for at least 10 years after the date of organ transplant and ensuring the serum sample is available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.12.C Authorization Requirement
Organ recovery teams may only recover organs that they have received authorization to recover. An authorized organ should be recovered if it is transplantable or a transplant

recipient is identified for the organ. If an authorized organ is not recovered, the host OPO must document the specific reason for non-recovery. This policy does not apply to VCA transplants.

Recovery of vascularized composite allografts for transplant must be specifically authorized from individual(s) authorizing donation whether that be the donor or a surrogate donation decision-maker consistent with applicable state law. The specific authorization for VCA must be documented by the host OPO.

5.2 Maximum Mismatched Antigens
A transplant program may also specify the maximum number of mismatched antigens it will accept and any unacceptable antigens for any of its candidates. If a transplant program specifies these mismatched antigens, the OPTN Contractor will only offer organs from deceased donors with mismatched antigens equal to or less than the maximum specified. This policy does not apply to VCA transplants.

5.4.B Order of Allocation
The process to allocate deceased donor organs occurs with these steps:

1. The match system eliminates candidates who cannot accept the deceased donor based on size or blood type.
2. The match system ranks candidates according to the allocation sequences in the organ allocation policies.
3. OPOs must first offer organs to potential recipients in the order that the potential recipients appear on a match run.
4. If no transplant program on the initial match run accepts the organ, the host OPO may give transplant programs the opportunity to update their candidates' data with the OPTN Contractor. The host OPO may run an updated match run and allocate the organ according to the updated candidate data.
5. If no transplant program within the DSA or through an approved regional sharing arrangement accepts the organ, the Organ Center will allocate an abdominal organ first regionally and then nationally, according to allocation Policies. The Organ Center will allocate thoracic organs according to Policy 6: Allocation of Hearts and Heart-Lungs and Policy 10: Allocation of Lungs.
6. Members may export deceased donor organs to hospitals in foreign countries only after offering these organs to all potential recipients on the match run. Members must submit the Organ Export Verification Form to the OPTN Contractor prior to exporting deceased donor organs.

This policy does not apply to VCA transplants; instead, members must allocate VCAs according to Policy 12.2: VCA Allocation.

5.5.A Receiving and Reviewing Organ Offers
Transplant hospitals must view organ offers and respond to these offers through the match system. The previous sentence does not apply to VCA transplants.
The transplanting surgeon at the receiving transplant hospital is responsible for ensuring the medical suitability of organs offered for transplant to potential recipients, including compatibility of deceased donor and candidate blood types (and donor subtype, when used for allocation).

5.5.B Time Limit for Acceptance
A transplant hospital must access deceased donor information in the match system within one hour of receiving the initial organ offer notification. If the transplant hospital does not access the match system within this time, the offer will be considered refused.

Transplant hospitals must either accept or refuse the organ within one hour of accessing the deceased donor information required for an organ according to Policy 2.3: Evaluating and Screening Potential Deceased Donors. If the transplant hospital does not respond within this time, the offer expires and the organ may be offered to the transplant hospital for the candidate that appears next on the match run.
This policy does not apply to VCA transplants.

Policy 12: Allocation of Vascularized Composite Allografts

12.1 Waiting Time

Waiting time for VCA candidates begins when the candidate is registered on the waiting list. For those candidates registered prior to September 1, 2014, waiting time will begin when the transplant hospital requests that the OPO actively seek a donor for an identified VCA candidate.

12.2 VCA Allocation

The host OPO will offer VCAs to candidates with compatible blood type willing to accept a VCA with similar physical characteristics to the donor. The OPO will offer VCAs to candidates in the following order:

1. Candidates that are within the OPO's region.
2. Candidates that are beyond the OPO's region.

Within each classification, candidates are sorted by waiting time (longest to shortest).
When a VCA is allocated, the host OPO must document 1) how the organ is allocated and the rationale for allocation and 2) any reason for organ offer refusals.

14.6 Registration and Blood Type Verification of Living Donors before Donation

Recovery hospitals must use source documents from both an initial and second determination blood typings and subtypings (when used to determine transplant compatibility), to enter the living donor's blood type data on the Living Donor Feedback Form. Additionally, each living donor program must develop and comply with a protocol to verify that the living donor's blood type and type was correctly entered on the Living Donor Feedback Form with both the initial and second determination blood typing and subtyping source documents by an individual other than the person initially entering the donor's blood type data.
Recovery hospitals must document that each blood typing and subtyping entry was performed according to the program's protocol and must maintain this documentation.
This policy does not apply to VCA transplants.

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. Table 18-1 shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.
This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased Donor Registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the *recipient feedback*	For each transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	*Deceased donor feedback*	5 business days after the procurement date	
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital

The following member:	Must submit the following materials to the OPTN Contractor:	Within:	For the following groups:
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	*See Policy 18.5.A: Reporting Requirements after Donation*	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60-days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60-days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24-hours after the transplant	For each recipient transplanted by the hospital
Transplant hospitals	*Recipient malignancy* (PTM)	30-days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	For each recipient, with a reported malignancy, that is followed by the hospital
Transplant hospitals	*Transplant candidate registration* (TCR)	30-days after the transplant hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient status at a time as close as possible to the specified transplant event anniversary. Table 18-2: Timely Data Collection sets standards for when the member must collect the data from the patient.

This policy does not apply to VCA transplants.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	*Living donor follow-up* (LDF)	within the 60-days prior to or after the form due date

18.3 Recording and Reporting the Outcomes of Organ Offers

The allocating OPO and the transplant hospitals that received organ offers share responsibility for reporting the outcomes of all organ offers. OPOs are responsible for reporting the outcomes of organ offers to the OPTN Contractor within 30 days of the match run date. OPOs, transplant hospitals, and the OPTN Contractor may report this information. The OPO or the OPTN Contractor must obtain PTR refusal codes directly from the physician, surgeon, or their designee involved with the potential recipient and not from other personnel.

If the OPO reports the refusal code, then the transplant hospital has 45 days from the match run date, to validate the refusal code by either confirming or amending the refusal code. If the OPO and transplant hospital report different refusal codes, then the OPTN Contractor will use the transplant hospital's refusal code for data analysis purposes.

If the OPTN reports the refusal code, then the transplant hospital will not be required to validate the refusal code.

This policy does not apply to VCA organ offers; instead, members must document VCA offers according to Policy 12.2: VCA Allocation.

VCA Transplant Program Contact Information for Organ Offers Worksheet

Transplant Hospital (Enter transplant hospital name or 4-character UNOS identification code)	
VCA Organ: Craniofacial	
Primary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
Secondary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
VCA Organ: Upper Limb	
Primary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
Secondary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
VCA Organ: Lower Limb	
Primary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
Secondary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	

VCA Organ: Abdominal Wall	
Primary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
Secondary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
VCA Organ: Other	
VCA Organ (Other, Specify)	
Primary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	
Secondary Contact:	
First Name	
Last Name	
Phone Number 1	
Phone Number 2	
Email	

VCA Candidate Registration Worksheet

Transplant Hospital	
Candidate Information	
VCA Organ(s) (Select all that apply)	☐ Upper Limb, Left ☐ Upper Limb, Right ☐ Craniofacial ☐ Other ☐ Lower Limb, Left ☐ Lower Limb, Right ☐ Abdominal Wall
If Applicable, Specify Other VCA Organ(s)	
ABO (Policy requires you to review source documents from two separate ABO typings to verify that the ABO is correctly entered for this candidate)	○ A ○ A1 ○ A2 ○ B ○ AB ○ A1B ○ A2B ○ O
Name of staff member verifying ABO result & accuracy of entry on worksheet (Source documents that show identical ABO blood types must be submitted for the candidate to be registered)	
Last Name	
First Name	
Middle Initial	
SSN	
Date of Birth (M/D/YYYY)	
Gender	
Ethnicity/Race (Select all that apply)	☐ White/Caucasian ☐ Hispanic/Latino ☐ American Indian/Alaska Native ☐ Black/African American ☐ Asian ☐ Native Hawaiian/Pacific Islander
Skin Tone/Pigmentation	
Height at Registration (in)	
Weight at Registration (lbs)	
Calculated Panel Reactive Antibody (CPRA) at Registration (%)	
HLA Antigens	**A:** **A:** **Bw4:** **B:** **B:** **Bw6:** **DR:** **DR:** **DR51:** **C:** **C:** **DR52:** **DQB:** **DQB:** **DR53:**
OPO Notification Date (M/D/YYYY) (The date when the transplant hospital requested the OPO to actively seek a donor for this VCA candidate)	
Currently Registered on the Waiting List for Non-VCA Organ(s)?	
If Yes, What Organ(s)? (Select all that apply)	☐ Heart ☐ Lung ☐ Kidney-Pancreas ☐ Liver ☐ Pancreas Islet ☐ Heart-Lung ☐ Kidney ☐ Pancreas ☐ Intestine
Donor Acceptance Information (limited to 500 characters) List any additional information here, such as if the upper extremities are above/below the elbow, if partial face, etc.	
Donor Exclusionary Criteria (limited to 500 characters) List any exclusionary criteria here, such as serology results, unacceptable antigens, etc.	
Name of staff member verifying worksheet information	

Please review the data before submitting via secure email to UNOS (vca@unos.org)

VCA Candidate Removal Worksheet

Candidate Information	
Transplant Hospital	
UNOS VCA Candidate ID	
Last Name	
SSN	
Date of Birth (M/D/YYYY)	
Removal Information	
Removal Date (M/D/YYYY)	
Removal Reason	
If "Other" Removal Reason, Specify	
VCA Organ(s) to be Removed (Select all that apply)	☐ Upper Limb, Left ☐ Upper Limb, Right ☐ Craniofacial ☐ Other ☐ Lower Limb, Left ☐ Lower Limb, Right ☐ Abdominal Wall
If Applicable, Specify Other VCA Organ(s) to be Removed	
If Candidate Died, Date of Death (M/D/YYYY)	
Cause of Death	
If Candidate was Transplanted, Date of Transplant (M/D/YYYY)	
Recovering OPO	
UNOS Donor ID	

Please review the data before submitting via secure email to UNOS (vca@unos.org)

At-a-Glance

Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs)

- **Affected/Proposed Policy:** OPTN Policies 18.1 and 18.2

- **Vascularized Composite Allograft (VCA) Transplantation Committee**

  There is no systematic data collection for VCA transplants in the U.S. The current proposal addresses the new data collection for VCA transplants. VCA-specific data elements have been identified for collection at the time of transplant and follow-up. The intervals for data collection were drawn from those intervals for other organ-specific Tiedi® forms. As an interim solution, VCA recipient data will be collected outside of UNet℠. The database used to collect this information will be managed by UNOS and can be queried to assess member compliance with OPTN policies and bylaws. The proposed updates to OPTN Policies 18.1 and 18.2 add specific data submission requirements for VCA candidate list, registration removal, transplant recipient registration, and transplant recipient follow-up information.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates

- **Number of Potential Candidates Affected**
  In February 2014, all OPOs responded to a survey given by AOPO asking to describe actual and planned VCA activity in their DSA. The survey found that 28 patients had received VCA transplants at 11 different transplant centers and that nine patients at six different transplant centers were awaiting transplant. The survey also indicated that five of the 11 centers already having performed a VCA transplant had plans to expand their program to additional VCA graft types, and nine additional transplant centers indicated their plan was to begin performing VCA transplants. As of August 29, 2014, there were 15 OPTN approved VCA transplant hospitals and seven VCA candidates registered on the OPTN waiting list.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal meets two of the six goals outlined in the OPTN Strategic Plan:

  Goal 3: Improve survival for patients
  Goal 4: Promote transplant patient safety

Establishing VCA data collection and submission requirements:

- Provides consistency and structure to VCA data collection in the U.S.
- Centralizes data collection to a single source to broadly assess:
  - Recipient post-transplant outcomes.
  - Effectiveness of VCA allocation policy.
- Allows for collection of data on VCA transplants that have occurred historically in the U.S., thereby increasing the data available for this transplant field.
- Addresses the advancing field of transplantation by responding to a new area of transplant clinical practice.

Data Collection and Submission Requirements for Vascularized Composite Allografts (VCAs)

Affected/Proposed Policy: OPTN Policies 18.1 (Data Submission Requirements) and 18.2 (Timely Submission of Data)

Vascularized Composite Allograft (VCA) Transplantation Committee

Public Comment Response Period: September 29, 2014 to December 5, 2014

Summary and Goals of the Proposal:

To date, there is no systematic, centralized data collection for VCA transplants in the U.S. The current proposal addresses the first attempt to collect transplant and follow-up data on VCA recipients for the immediate purposes of evaluating outcomes and ensuring patient safety. VCA-specific data elements have been identified for collection at the time of transplant and follow-up. As the data collection evolves, data elements may be added, amended, or deleted in the future based on input from the transplant community.

Additionally, this proposal updates OPTN data submission requirements. The proposed policies contain the following:

- Specific data elements to be collected on VCA recipients at transplant and follow-up
- Members responsible for submitting VCA organ transplant candidate, recipient, and donor data
- The time period that VCA organ transplant candidate, recipient, and donor data must be submitted to the OPTN

Background and Significance of the Proposal:

On July 3, 2014, the OPTN Final Rule (42 CFR part 121) was amended to add VCAs under the definition of an "organ"[1], thereby granting the OPTN oversight over VCA recovery, allocation, and transplantation. Under the Final Rule, the OPTN shall:

I. Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
II. Maintain records of all transplant candidates, all organ donors and all transplant recipients;
III. Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested;
IV. In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.

Additionally, the OPTN is required by statute to:

I. Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary.

[1] U.S. Government Printing Office, Electronic Code of Federal Regulations, 42 CFR part §121.2, August 14, 2014, http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121_main_02.tpl

II. Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

In order to properly fulfill the requirements set forth by the Secretary of Health and Human Services, the OPTN Final Rule, and the National Organ Transplant Act (NOTA), the VCA Committee recommended a list of data elements to collect on VCA candidates and recipients. The goals of this data collection include:

- Centralizing data collection on all VCA transplants performed in the U.S. in order to:
    - Support the scientific advancement of VCA transplantation in the U.S.
    - Comply with requirements of the OPTN Contract
- Aligning VCA data submission requirements with requirements for other, non-VCA organs

The VCA Data Subcommittee ("the Data Subcommittee") met on May 28, 2014 to review data elements to be collected on the VCA Registration and Removal worksheets outside of Tiedi®. Additionally, the Data Subcommittee reviewed the VCA Candidate List that contained donor and potential recipient matching for VCA organ allocation to be implemented outside of DonorNet®. UNOS staff developed an interim solution for data linkages between the worksheets and VCA organ allocation lists to promote wider access to VCA organs while maintaining the security of the VCA candidate list. This interim solution for VCA waiting list and allocation has been effective since July 3, 2014.

The VCA Committee discussed VCA recipient data collection. As the area of VCA transplantation is emerging, the Committee views all of the proposed data elements as critically important. Central to this was adherence to the OPTN Principles of Data Collection that were approved by the OPTN/UNOS Board of Directors in 2006. The primary goal of these principles is to improve patient outcomes by:

- Developing transplant, donation, and allocation policies,
- Determining if institutional members are complying with policies,
- Determining member-specific performance,
- Ensuring patient safety when no alternative sources of data exist, and
- Fulfilling the requirements of the OPTN Final Rule

The Committee asked the VCA Data Subcommittee to identify any additional VCA-specific data elements that should be collected on recipients. The Data Subcommittee met on July 18, 2014 and recommended additional VCA-specific data elements for collection, including general physical and mental health, VCA organ functions, and major complications. The Subcommittee also recommended collecting data at intervals identical to those for other, non-VCA organs (at discharge or six weeks post-transplant, whichever is first; at the six month anniversary; and annually thereafter).

Since OPTN data collection forms must be reviewed and approved by the Office of Management and Budget (OMB). The draft list of data elements was submitted to HRSA on July 31, 2014 for OMB review. Data submission on VCA transplants performed prior to July 3, 2014 will be optional. Data submission on VCA transplants performed after July 3, 2014 will be mandatory.

Prior to July 3, 2014, data collection and data submission for VCA candidates and recipients was not possible due to technical limitations of the existing electronic infrastructure used by the OPTN. As such, a policy waiver was implemented by the OPTN/UNOS Board of Directors for VCA data

submission. Because of the pending statutory change at the time, these policy changes were approved by the OPTN/UNOS Board of Directors during its June 23-24, 2014 meeting with a "sunset" date on September 1, 2015. Those initial policies, including the waiver in Policies 18.1 and 18.2, are being released for public comment at the same time as this proposal. Due to time constraints, the proposal will be considered by the Executive Committee on behalf of the BOD at the end of March 2015 or early April 2015.

Mechanism for Data Collection

Programming a new organ type into the existing electronic infrastructure used by the OPTN is a significant endeavor. In light of the time available before the regulatory change and the anticipated low number of VCA transplants that may occur annually, it was determined that high level data integration was not possible at this time. In collaboration with the VCA Committee, UNOS staff developed VCA candidate registration/removal, allocation, and transplant data collection that would function in a system outside of DonorNet®, Wait List℠ and Tiedi®. The transplant data collection will be managed through an Access database and will only be accessible to VCA transplant program staff through a secure SharePoint website.

In addition to the changes above, this proposal includes a cleanup of the introductory text in Policy 18.1 that is consistent with the principles used to draft the 2013 plain language rewrite; these changes do not substantively change the requirements of Policy 18.1.

Supporting Evidence:

A survey of Organ Procurement Organizations (OPOs) was conducted in February 2014. The purpose of this survey was to assess the number of VCA transplants performed in the U.S. The survey results identified 28 hand and face transplants performed at 11 transplant hospitals since 1999[2]:

- 6 face transplants
- 7 bilateral upper limb transplants
- 14 unilateral upper limb transplants
- 1 multiple VCA transplant – a face and a bilateral upper limb

A literature review identified 15 VCA grafts used in the reconstruction of the abdominal wall have been transplanted at two transplant hospitals[3]. However, the time period for these procedures is unknown. In each case, the authors report the abdominal wall transplants were performed in recipients who received intestinal transplants. It is anticipated the actual number of VCA grafts used in the reconstruction of the abdominal wall to be much higher.

Given the reported 43 instances of known VCA transplants in the U.S. and in the absence of outcomes and patient safety information following VCA transplants, it is critically important to have a centralized data collection system.

[2] Organ Procurement and Transplantation Network, Unpublished report, February 25, 2014.

[3] Selvaggi, G., Levi, D.M., Cipriani, R., Sgarzani, R., Pinna, A.D., and Tzakis, A.G., "Abdominal Wall Transplantation: Surgical and Immunologic Aspects", *Transplantation Proceedings*, (2014): 521.

Expected Impact on Living Donors or Living Donation:

The Secretary of Health and Human Services responded to the possibility of a living VCA donor in the amendment to the OPTN Final Rule. The Secretary affirmed that oversight of living donors was under the auspices of the OPTN. The definition of a VCA in both the OPTN Policies and Bylaws was adopted from the Final Rule. This Final Rule definition intentionally did not prohibit the possibility of living VCA donors. Cases of live VCA donations have been reported in Europe[4], however there are no candidates for living VCA donors registered with the OPTN.

Expected Impact on Specific Patient Populations:

This will impact all VCA candidates and recipients.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal meets two of the six goals outlined in the OPTN Strategic Plan:

Goal 3: Improve survival for patients
Goal 4: Promote transplant patient safety

Establishing centralized VCA data collection and data submission requirements:

- Provides consistency and structure to VCA data collection in the U.S.
- Centralizes data collection to a single source to:
    -
    -
    -
    -
    -
- Allows collection of data on VCA transplants that have occurred historically in the U.S.
- Addresses the changing field of transplantation by responding to a new area of transplant clinical practice

Plan for Evaluating the Proposal:

Periodic tabulations of data elements will be provided to the VCA Committee when sufficient data are available, including, but not limited to:

- Patient socio-demographics and clinical characteristics
- General physical and mental health
- Organ function
- Graft and patient survival
- Immunosuppression
- Acute Rejection

[4] Brannstrom, M., Johannesson, L., Gabel, M., Kvarnstrom, N., Tzakis, A., Olausson, M. "The First Clinical Trial of Uterus Transplantation: Surgical Technique and Outcome*", American Journal of Transplantation*, (2014): 44, http://onlinelibrary.wiley.com/doi/10.1111/ajt.12877/pdf

Additional Data Collection:

Additional data collection will be required as a result of this proposal. Tables 1 and 2 in **Exhibit A** list the justification(s) for each data element to be collected on the TRR and TRF forms according to the OPTN Principles of Data Collection (PODCs). The PODCs were determined based on the immediate purposes of VCA transplant and post-transplant data collection including outcomes evaluation and ensuring patient safety. Because VCA is a life enhancing procedure, collecting data pertinent to the risks of immunosuppression are essential to protect patient safety. As the field advances and more experience is gained, some of the elements may be used for other purposes such as determining allocation policy, payment for insurance coverage (including Medicare coverage) for the procedure and immunosuppressive medications, or determining member-specific performance.

The data elements that are proposed to be collected on the VCA TRR and TRF forms include common data elements already collected on the TRR and TRF forms for other non-VCA organs. Additionally, the TRR and TRF forms will capture information that is particularly relevant to VCA organ transplants such as source of payment for the transplant (including grant and institutional funding), general physical and mental health, and VCA organ functions. Organ functions will be specific to craniofacial and upper limb, most of which will be important to capture on the follow-up forms. In the absence of systematic information about outcomes following VCA transplants in the U.S., the data elements proposed in this policy will be very critical for developing allocation policy and ensuring patient safety

Expected Implementation Plan:

Member OPOs and Transplant Hospitals will need to be familiar with the requirements of OPTN Policies 18.1 and 18.2 pertaining to submission of information on organ donors from whom VCA grafts are recovered, VCA allocation, VCA registration removal, and VCA recipients.

Member transplant programs will:

1. Continue to register and remove VCA candidates by using the worksheets provided by the OPTN as outlined in Table 18-1.
2. Need to complete TRR and TRF forms for VCA recipients and submit completed forms as outlined in Table 18-1.
3. Need to obtain credentials for accessing the VCA database in order to submit TRR and TRF forms.

Member OPOs will:

1. Continue to use DonorNet® to register all donors, including those donors from whom only VCA grafts may be recovered.
2. Continue to complete Donor Feedback and Deceased Donor Registration forms for all donors, including those donors from whom only VCA grafts are recovered as outlined in Table 18-1.
3. Submit completed VCA Candidate Lists to the OPTN as outlined in Table 18-1.

Additional programing in DonorNet®, Wait List℠, or Tiedi® is not anticipated at this time.

Communication and Education Plan:

Since this policy proposal is about data collection of VCA organs transplants, the audience is limited to the transplant teams that have approved VCA programs and OPOs. Thus far, we have reached this audience directly with emails and letters. While the number of VCA programs remains small, this is a good way to reach them. Additionally, online articles will inform the transplant community at large as we begin to collect data on VCA transplants through the OPTN.

Communication & Education Activities

- Policy notice
- E-newsletter/member archive article
- Presentation at Regional Meetings
- Instructional programs as needed
- Articles/Guidance Documents on the Web and Member Archive

Compliance Monitoring:

The following routine monitoring will continue to apply to OPTN members:

At OPOs, site surveyors will review rates of compliance with submission dates for Deceased Donor Registration (DDR) forms submitted to the OPTN within the review timeframe.

The following new routine monitoring may apply to OPTN members:

For each deceased donor VCA organ offered to a potential VCA recipient, UNOS staff will verify that the allocating OPO submitted a VCA candidate list to the OPTN:

- in the required time period
- containing all required refusal, bypass, and acceptance information

Any data submitted to the OPTN may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

18.1 Data Submission Requirements

~~OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.~~

Members must report data to the OPTN Contractor ~~using standardized forms~~ according to~~.~~ *Table 18-1 below*. ~~shows the member responsible for submitting each data form and when the Member must submit the following materials to the OPTN Contractor.~~

~~This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.~~

Table 18-1: Data Submission Requirements

This ~~e following~~ member:	***Must submit the following ~~materials~~ to the OPTN Contractor:***	***Within:***	***For ~~the following groups~~:***
Histocompatibility Laboratory	Donor histocompatibility (DHS)	30 days after the OPO submits the deceased donor registration	~~For e~~Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the laboratory
Histocompatibility Laboratory	Recipient histocompatibility (RHS)	Either of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the recipient feedback	~~For e~~Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
OPOs, all	Death notification records (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	~~For a~~All imminent neurological deaths and eligible deaths in its DSA
OPOs, all	Monthly Donation Data Report: Reported Deaths	30 days after the end of the month in which a donor hospital reports a death to the OPO	~~For a~~All deaths reported by a hospital to the OPO
Allocating OPO	Potential transplant recipient (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	~~For e~~Each deceased ~~organ~~ donor heart, intestine, kidney, liver, lung, or pancreas that is offered to a potential recipient
Allocating OPO	VCA Candidate List	30 days after the procurement date	Each deceased donor VCA organ that is offered to a potential VCA recipient
Host OPO	Deceased donor feedback	5 business days after the procurement date	All deceased donors

This ~~e following~~ member:	***Must submit the following ~~materials~~ to the OPTN Contractor:***	***Within:***	***For ~~the following groups~~:***
Host OPO	Deceased donor registration (DDR)	30 days after the deceased donor feedback form is submitted and disposition is reported for all organs	~~For a~~ All deceased donors ~~and authorized but not recovered potential deceased donors~~
Recovery Hospitals	Living donor feedback	The time prior to donation surgery	~~For~~ ~~e~~Each potential living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	Living donor registration (LDR)	60 days after the Recovery Hospital submits the living donor feedback form	~~For~~ ~~e~~Each living donor organ recovered at the hospital This does not apply to VCA donor organs
Recovery Hospitals	Living donor follow-up (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	~~For~~ ~~e~~Each living donor organ recovered at the hospital This does not apply to VCA donor organs
Transplant hospitals	Organ specific transplant recipient follow-up (TRF)	1. 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14 days from notification of the recipient's death or graft failure	~~For~~ ~~e~~Each recipient followed by the hospital

This ~~e following~~ member:	***Must submit the following ~~materials~~ to the OPTN Contractor:***	***Within:***	***For ~~the following groups~~:***
Transplant hospitals	Organ specific transplant recipient registration (TRR)	60 days after transplant hospital ~~submits the recipient feedback form~~ removes the recipient from the waiting list	~~For~~ ~~e~~Each recipient transplanted by the hospital
Transplant hospitals	Liver Post-Transplant Explant Pathology	60 days after transplant hospital submits the recipient feedback form	~~For~~ ~~e~~Each liver recipient transplanted by the hospital
Transplant hospitals	Recipient feedback	~~24 hours~~ 1 day after the transplant	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital
Transplant hospitals	Candidate Removal Worksheet	1 day after the transplant	Each VCA recipient transplanted by the hospital
Transplant hospitals	Recipient malignancy (PTM)	30 days after the transplant hospital reports the malignancy on the transplant recipient follow-up form	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas recipient~~,~~ with a reported malignancy~~,~~ that is followed by the hospital
Transplant hospitals	Transplant candidate registration (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	~~For~~ ~~e~~Each heart, intestine, kidney, liver, lung, or pancreas candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients is based on recipient status at a time as close as possible to the specified transplant event anniversary.

Table 18-2: Timely Data Collection sets standards for when the member must collect the data from the patient.

~~This policy does not apply to VCA transplants.~~

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or six-weeks following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or six-weeks following the transplant date, whichever is first This does not apply to VCA transplants
Recovery hospital	*Living donor follow-up* (LDF)	60-days before or after the six-month, 1-year, and 2-year anniversary of the donation date This does not apply to VCA transplants

Table 1. Principle(s) of Data Collection for Data Elements Collected on VCA Transplant Recipient Registration (TRR) Forms

Principles of Data Collection:
A = Develop transplant, donation, and allocation policies
C = Determine if institutional members are complying with policies
P = Determine member-specific performance
S = Ensure patient safety when no alternative sources of data exist
F = Fulfil the requirements of the OPTN Final Rule

Field Label	Principle(s) of Data Collection
Recipient First Name (Display Only - Cascades from Removal Worksheet)	
Recipient Last Name (Display Only - Cascades from Removal Worksheet)	
Recipient Middle Initial (Display Only - Cascades from Removal Worksheet)	
DOB (Display Only - Cascades from Removal Worksheet)	
SSN (Display Only - Cascades from Removal Worksheet)	
Gender (Display Only - Cascades from Removal Worksheet)	
HIC (Not Required – If Available)	
Transplant Date (Display Only - Cascades from Removal Worksheet)	
State of Permanent Residence	F
Permanent Zip Code	F
Recipient Center (Display Only - Cascades from Removal Worksheet)	
Lead Reconstructive Surgeon Name	C, S
Lead Reconstructive Surgeon NPI#	C, S
UNOS Donor ID # (Display Only - Cascades from Removal Worksheet)	
Donor Type (Display Only - Cascades from Removal Worksheet)	
OPO (Display Only - Cascades from Removal Worksheet)	
Date of Admission to Transplant Center	A
Date of Discharge from Hospital	A
Date Last Seen, Retransplanted, or Death	A, F
Patient Status	A, F
Primary Cause of Death	A, S
Primary Cause of Death - Other, Specify	A, S
Highest Education Level	A
Working for income	A
Working for income - If Yes, indicate the recipient's working status	A
Working for income - If No, Not Working Due To	A
Grant Funding	F
Institutional Funding	F
Primary Insurance	F
Primary Insurance - Foreign Government, Specify	F
Secondary Source of Payment	F
Height (inches)	A
Weight (lbs)	A
BMI (Body Mass Index) (Display Only - Calculated)	
Primary Diagnosis for Transplant	A
Primary Diagnosis for Transplant - Other, Specify	A
Amount of Tissue Loss: Craniofacial	A
Amount of Tissue Loss: Craniofacial for Partial Face - Specify anatomic structures missing	A
Amount of Tissue Loss: Craniofacial - Other, Specify	A
Amount of Tissue Loss: Abdominal Wall (cm2)	A
Amount of Tissue Loss: Other	A
Amount of Tissue Loss: Other, Specify	A
Level of Amputation: Upper Limb	A

Field Label	Principle(s) of Data Collection
Level of Amputation: Upper Limb - Other, Specify	A
Level of Amputation: Lower Limb	A
Level of Amputation: Lower Limb - Other, Specify	A
Previous Transplants (VCA or non-VCA organs)	A
Previous skin graft(s)	A
Was patient hospitalized during the last 90 days prior to the transplant admission	A
Medical Condition at time of transplant	A
Patient on Life Support	A
Patient on Life Support: Ventilator	A
Patient on Life Support: Other Mechanism – Specify (text)	A
HIV Serostatus	S
CMV Serostatus	S
HBV Core Antibody	S
HBV Surface Antigen	S
HCV Serostatus	S
EBV Serostatus	S
Any tolerance induction technique used	S
Pre-transplant blood transfusions	A
Number of pre-transplant pregnancies	A
Malignancies prior to transplant	S
Malignancies prior to transplant - If Yes, Specify Type	S
Serum Creatinine (mg/dL)	S
Hemoglobin A1c (%)	S
Calculated PRA (CPRA) at transplant (%)	A
Donor Crossmatch Result	A
Risk Factors: Coagulopathies	S
Risk Factors: Other, Specify (text)	S
Cognitive Development	S
Motor Development	S
SF-36: Physical Functioning (PF) Score	S
SF-36: Role-Physical (RP) Score	S
SF-36: Bodily Pain (BP) Score	S
SF-36: General Health (GH) Score	S
SF-36: Vitality (VT) Score	S
SF-36: Social Functioning (SF) Score	S
SF-36: Role-Emotional (RE) Score	S
SF-36: Mental Health (MH) Score	S
DASH Score (for Upper Limb)	S
Carroll Test Score (for Upper Limb)	S
Multiple Graft Recipient	A
Were extra allograft vessels/nerve/tissue from outside the donated graft used in the transplant procedure	A
Surgical Procedure	A
Warm Ischemia Time	A
Cold Ischemia Time	A
Graft Status	A, S
Date of Graft Failure	A, S
Cause of Graft Failure: Thrombosis	A, S
Cause of Graft Failure: Acute Rejection	A, S
Acute Rejection - Banff score	A, S
Acute Rejection - Visual skin changes	A, S
Cause of Graft Failure: Chronic Rejection	A, S
Chronic Rejection - Visual skin changes	A, S

Field Label	Principle(s) of Data Collection
Cause of Graft Failure: Ischemia	A, S
Cause of Graft Failure: Sepsis / Infection	A, S
Cause of Graft Failure: Trauma	A, S
Cause of Graft Failure: Patient requested removal	A, S
Cause of Graft Failure: Non-compliance: immunosuppression	A, S
Cause of Graft Failure: Non-compliance: rehabilitation	A, S
Cause of Graft Failure: Non-compliance: level of activity	A, S
Cause of Graft Failure: Other, Specify (text)	A, S
Serum Creatinine (mg/dL)	S
Hemoglobin A1c (%)	S
Major Transplant Complications: Arterial Thrombosis	S
Major Transplant Complications: Venous Thrombosis	S
Major Transplant Complications: More than 5 pRBC (packed red blood cells) units	S
Major Transplant Complications: Cardiac arrest	S
Major Transplant Complications: DIC (Disseminated intravascular coagulation)	S
Major Transplant Complications: Graft/reperfusion syndrome	S
Major Transplant Complications: Other, Specify (text)	S
Did patient have any acute rejection episodes between transplant and discharge	A, S
Did patient have any acute rejection episodes between transplant and discharge - Number of treated episodes	A, S
{For each episode} Date of rejection diagnosis	A, S
{For each episode} Treatment for acute rejection	A, S
{For each episode} Visual skin changes	A, S
{For each episode} Was biopsy done to confirm acute rejection	A, S
{For each episode} Banff Score	A, S
Treatment: Antiviral Prophylaxis	S
Treatment: Antibacterial Prophylaxis	S
Treatment: Antifungal Prophylaxis	S
Treatment: Peri-operative anticoagulation	S
Topical: Immunosuppression medications	S
Topical: Immunosuppression medications - Other, Specify (text)	S
Topical: Maintenance indication	S
Topical: Anti-rejection indication	S
Non-Topical: Immunosuppression medications	S
Non-Topical: Immunosuppression medications - Other, Specify (text)	S
Non-Topical: Induction indication	S
Non-Topical: Number of days of induction	S
Non-Topical: Maintenance indication	S
Non-Topical: Anti-rejection indication	S

Table 2. Principle(s) of Data Collection for Data Elements Collected on VCA Transplant Recipient Follow-up (TRF) Forms

Principles of Data Collection:

Field Label	Principle(s) of Data Collection
Recipient First Name (Display Only - Cascades from Removal Worksheet)	
Recipient Last Name (Display Only - Cascades from Removal Worksheet)	
Recipient Middle Initial (Display Only - Cascades from Removal Worksheet)	
DOB (Display Only - Cascades from Removal Worksheet)	
SSN (Display Only - Cascades from Removal Worksheet)	
Gender (Display Only - Cascades from Removal Worksheet)	
HIC (Display only - Cascades from TRR if available)	
Transplant Date (Display Only - Cascades from Removal Worksheet)	
State of Permanent Residence	F
Permanent Zip	F
Treating Reconstructive Surgeon Name	C, S
Treating Reconstructive Surgeon NPI#	C, S
Treating Transplant Physician Name	C, S
Treating Transplant Physician NPI#	C, S
Follow-up Care Provided By:	S
UNOS Donor ID # (Display Only - Cascades from Removal Worksheet)	
Donor Type (Display Only - Cascades from Removal Worksheet)	
OPO (Display Only - Cascades from Removal Worksheet)	
Date Last Seen, Retransplanted, or Death	A, F
Patient Status	A, F
Primary Cause of Death	A, F
Primary Cause of Death - Other, Specify	A, F
Has patient been hospitalized since the Last Patient Status Date	A
Number of Hospitalizations	S
Working for income	A
Working for income - If Yes, indicate the recipient's working status	A
Working for income - If No, Not Working Due To	A
Grant funding	F
Institutional funding	F
Primary Source of Payment	F
Primary Source of Payment - Foreign Government, Specify	F
Secondary Source of Payment	F
Cognitive Development	S
Motor Development	S
Psychosocial consult performed	S
SF-36: Physical Functioning (PF) Score	S
SF-36: Role-Physical (RP) Score	S
SF-36: Bodily Pain (BP) Score	S
SF-36: General Health (GH) Score	S
SF-36: Vitality (VT) Score	S
SF-36: Social Functioning (SF) Score	S
SF-36: Role-Emotional (RE) Score	S

Field Label	Principle(s) of Data Collection
SF-36: Mental Health (MH) Score	S
DASH Score (for Upper Limb)	S
Carroll Test Score (for Upper Limb)	S
Sensibility Test - Semmes Weinstein (for Upper Limb)	S
Sensory Test: 2 point discrimination (mm) (for Craniofacial)	S
Sensory Test: Patient can feel heat (for Craniofacial)	S
Sensory Test: Patient can feel cold (for Craniofacial)	S
Oral competence (for Craniofacial)	S
Corneal protection (able to open/close) (for Craniofacial)	S
Functional occlusion restored (for Craniofacial)	S
Decannulation (if the patient had a tracheostomy) (for Craniofacial)	S
Feeding Tube Removed (if patient had a feeding tube) (for Craniofacial)	S
Speaking rate (for Craniofacial)	S
Percent Intelligibility (for Craniofacial)	S
Height (inches)	A
Weight (lbs)	A
BMI (Body Mass Index) (Display Only – Calculated)	
Noncompliance: Immunosuppression	A, S
Noncompliance: Rehabilitation	A, S
Noncompliance: Level of Activity	A, S
Noncompliance: Other, Specify (text)	A, S
Graft Status	A, S
Date of Graft Failure	A, S
Cause of Graft Failure: Acute Rejection	A, S
Acute Rejection - Banff score	A, S
Acute Rejection - Visual skin changes	A, S
Cause of Graft Failure: Chronic Rejection	A, S
Chronic Rejection - Visual skin changes	A, S
Cause of Graft Failure: Ischemia	A, S
Cause of Graft Failure: Sepsis / Infection	A, S
Cause of Graft Failure: Trauma	A, S
Cause of Graft Failure: Patient requested removal	A, S
Cause of Graft Failure: Non-compliance: immunosuppression	A, S
Cause of Graft Failure: Non-compliance: rehabilitation	A, S
Cause of Graft Failure: Non-compliance: level of activity	A, S
Cause of Graft Failure: Other, Specify (text)	A, S
Serum Creatinine (mg/dL)	S
Hemoglobin A1c (%)	S
Donor Specific Antibodies (DSA)	A, S
Did patient have any acute rejection episodes during the follow-up period	A, S
If Yes - Number of treated episodes	A, S
{For each episode} Date of rejection diagnosis	A, S
{For each episode} Treatment for acute rejection	A, S
{For each episode} Visual skin changes	A, S
{For each episode} Was biopsy done to confirm acute rejection	A, S
{For each episode} Banff Score	A, S
Complications: New onset diabetes	S
Complications: Metabolic	S
Complications: Infectious	S
Complications: Other, Specify (text)	S
Post Transplant Malignancy	A, S
Post Transplant Malignancy Type: Donor Related	A, S

Field Label	Principle(s) of Data Collection
Donor Related - Diagnosis Date	S
Donor Related - Type of Tumor	S
Post Transplant Malignancy: Recurrence of Pre-Transplant Tumor	A, S
Recurrence of Pre-Transplant Tumor - Recurrence Date	S
Recurrence of Pre-Transplant Tumor - Type of pre-existing tumor	S
Recurrence of Pre-Transplant Tumor - Type of pre-existing tumor - Other, Specify	S
Post Transplant Malignancy: De Novo Solid Tumor	A, S
De Novo Solid Tumor - Diagnosis Date	S
De Novo Solid Tumor - Type of tumor(s)	S
De Novo Solid Tumor - Type of tumor(s) - Other, Specify	S
Post Transplant Malignancy: PTLD and Lymphoma	A, S
PTLD and Lymphoma - Diagnosis date	S
PTLD and Lymphoma – Pathology	S
PTLD and Lymphoma - Pathology - Other, Specify	S
Treatment: Antiviral	S
Treatment: Antibiotic	S
Treatment: Antifungal	S
Topical: Immunosuppression medications	S
Topical: Immunosuppression medications - Other, Specify (text)	S
Topical: Previous maintenance indication	S
Topical: Current maintenance indication	S
Topical: Anti-rejection indication	S
Non-Topical: Immunosuppression medications	S
Non-Topical: Immunosuppression medications - Other, Specify (text)	S
Non-Topical: Previous maintenance indication	S
Non-Topical: Current maintenance indication	S
Non-Topical: Anti-rejection indication	S

- **Affected/Proposed Bylaws:** Article 11.1.A (The Public Comment Period); 11.6 (Developing Organ Allocation Policies)

- **Executive Committee**

  This proposal includes changes to the OPTN Bylaws intended to improve the OPTN policy development process and provide the OPTN/UNOS Board of Directors and committees more flexibility in addressing different types of problems identified by the transplant community. The proposal includes the creation of two new policy development tracks designed to allow the OPTN/UNOS Board to address emergency and non-controversial issues in a more efficient and expedient manner, while continuing to maintain the OPTN's cornerstone principles of transparency and community consensus.

- **Affected Groups**
  No specific patient populations are affected. This will impact the manner in which the OPTN/UNOS Board and Committees schedule the public comment period on policy proposals.

- **Number of Potential Candidates Affected**
  Not applicable.

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal is intended to further the OPTN strategic goal of promoting efficient management of the OPTN and, in particular, the objective to improve responsiveness of OPTN policy to a changing environment.

Improving the OPTN Policy Development Process

Affected/Proposed Policy: Article 11.1.A (The Public Comment Period); 11.6 (Developing Organ Allocation Policies)

Executive Committee

Public Comment Response Period: September 29-December 5, 2014

Summary and Goals of the Proposal:

This proposal includes changes to the OPTN/UNOS Bylaws intended to improve the OPTN/UNOS policy development process and provide the OPTN/UNOS Board of Directors (the Board) and committees more flexibility in addressing different types of problems identified by the transplant community. The proposal includes the creation of two new policy development tracks designed to allow the OPTN/UNOS Board to address emergency and non-controversial issues in a more efficient and expedient manner, while continuing to maintain the OPTN's cornerstone principles of transparency and community consensus in the process. Specifically, the proposal includes the following:

- Clarifies the process the Board will follow to address 'emergency actions' that fall into one of the three below categories:

    1. A proposal necessitated by a pending statutory or regulatory change.
    2. A proposal required due to an emergent public health issue or patient safety factors.
    3. A proposal necessitated by a new medical device or technology that affects organ allocation.

    This proposed Bylaws change would clarify that the Board can take action on a policy change in these limited instances, but requires the Board to specify a sunset date that is no more than 12 months beyond the policy's effective date and distribute the policy for public comment no more than 6 months after approval.

- Creates the following new process for non-controversial and routine policy changes:

    1. The sponsoring Committee distributes a public comment proposal (following the normal policy development process) for a new or existing policy and specifies in the policy language areas that will be eligible for future expedited updates.
    2. The Board approves the proposal, including policy language specifying that the particular policy section is eligible for expedited updates.
    3. At a later date, the sponsoring Committee develops a proposal for expedited action.
    4. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
    5. The sponsoring committee considers public comments and recommends final adoption of the proposal.
    6. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or four members of the Board of Directors, then the sponsoring Committee will notify the

Executive Committee of the objections and the proposal will follow the normal OPTN policy development process.

7. If the specified number of objections in #6 above are not received during the public comment period, then the process will proceed as follows:
    a) If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership unless a different date is specified.
    b) If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to 11.2 Submitting Policy Proposals to the Board of Directors. This will require a review by the Board or Executive Committee before the proposal is adopted.

Background and Significance of the Proposal:

One of the key goals in the current OPTN strategic plan is to promote the efficient management of the OPTN. As part of achieving this goal, the Board identified an objective of "improving responsiveness of OPTN policy to a changing environment". In 2013, the OPTN/UNOS Executive Committee ("the Committee") appointed a policy development process improvement workgroup ("workgroup") to examine the OPTN policy development process and recommend changes for improvement. This workgroup was comprised of Executive Committee members that represented different OPTN member perspectives (transplant programs, OPOs, and histocompatibility laboratories), as well as a few former OPTN/UNOS committee chairs who have experience with the current policy development process. The workgroup met several times from January-May 2014 and identified several problems with the current process. This proposal addresses some of the problems identified through this effort.

<u>The Current OPTN Policy Development Process</u>

It's important to note that the OPTN policy development process is governed by the National Organ Transplant Act (NOTA), the OPTN Final Rule, the OPTN Contract, and the OPTN Bylaws. All of these documents specify different rules that must be followed in the process. The Executive Committee considered each of these requirements in formulating this proposal.

The normal policy development process can be described, at a high level, in the following steps:

1. An OPTN/UNOS Committee defines a problem that exists in the transplant community.
2. The Committee discusses the problem and possible solutions, collaborating with other interested stakeholders.
3. The Committee presents the problem and possible solutions to the OPTN/UNOS Policy Oversight and Executive Committees to get approval to deploy OPTN resources to address the problem.
4. If approval is obtained, the Committee finalizes the proposal and solutions for a public comment proposal.
5. The Committee distributes the proposal for public comment (this includes presenting the proposal at all regional meetings and to other OPTN Committees for feedback). The public comment period is currently, on average, around 90 days long.
6. Once the public comment period closes, the Committee reviews all the comments, collaborates with interested stakeholders, and makes a final recommendation to the Board of Directors.
7. The Board of Directors considers the Committee recommendations, along with all the comments, and takes final action on the proposal.

At present, it takes an OPTN Committee approximately 1 ½ to 2 years to complete this full process.

The Executive Committee determined that the current 'one size fits all' process for policy development does not provide flexibility for addressing different types of problems, especially those that are urgent or non-controversial. This model is inefficient and does not meet the needs of the transplant community. The Committee reviewed other policy development models to determine whether multiple policy development tracks could help the OPTN in being more responsive to needed policy changes. As a result of the review, the Executive Committee is recommending Bylaws changes to create two new policy development processes.

Emergency Actions

The Committee discussed recent situations that have necessitated the Board or Executive Committee (acting on behalf of the Board) take immediate action to change or create a policy. The recent Final Rule change to include vascular composite allografts (VCA) under the definition of organ allocation necessitated such action, because the federal regulation became effective before new VCA membership and allocation rules could be approved and implemented under the normal OPTN policy development process. The recent controversy around pediatric and adolescent lung allocation rules is another example. The Executive Committee took emergency action to address this problem. Finally, the Committee discussed the example of Total Artificial Heart (TAH) where a change in medical device required emergency policy changes.

In each of these cases, the Board or the Executive Committee took action to approve policy changes, instituted a sunset date for the policy, and subsequently distributed the policy for public comment. The Committee is proposing that the OPTN Bylaws be amended to specify the process that such emergency actions follow. This Bylaws change would require the Board to specify a sunset date that is no more than 12 months beyond the policy's effective date and distribute the policy for public comment no more than 6 months after approval. Once the Board approves a new policy, the changes would be communicated to the transplant community consistent with communication of other changes (for example, through the policy notice) and often includes outreach to regions or specific programs that will be impacted.

The Committee considered making these timelines even shorter, however, a shorter timeline for public comment and approval is not realistic under the current policy development calendar. Even with improvements being made to the calendar (see Other Solutions below), these are minimum timeframes for public comment and Board approval.

Expedited, Non-Controversial Actions

The Committee also determined that the normal policy development process is too lengthy for non-controversial and routine policy changes. There were several examples discussed for this category. One example was for complex allocation algorithms like the Calculated Panel Reactive Antibody (CPRA) score, used in kidney allocation, where frequencies are based on a cohort of deceased donors from a specific time period. The time period used for the donor cohort needs to be updated in order for the CPRA score to be as accurate as possible. These algorithms commonly become outdated because of the long process that must be followed. Another example discussed was a section in OPTN Bylaws, Appendix C, which requires histocompatibility laboratories to comply with requirements found in documents published by histocompatibility accrediting agencies. The Bylaws reference a date certain for these documents, in order to

ensure that any changes to these requirements are released for public comment. The lengthy policy development process results in the date referenced consistently being one or more years behind. There has previously been little to no dissent in the public comment period for these proposed updates, but there is currently no other option for getting the update approved in a more efficient manner.

The Committee reviewed other policy development models for examples that allow for expedited approval of such changes. After review, the Committee is recommending changes to the Bylaws that would create an expedited policy development track. The Committee discussed the importance of this process only being utilized for changes that had little to no controversy and defined a process that includes mechanisms to ensure this. Other rulemaking bodies that employ expedited pathways typically limit the pathway to non-controversial proposals. The most frequent methods to limit the availability of the pathway are to 1) have a body review and approve the proposal for expedited pathway before it is released 2) have a body review and approve the proposal for expedited pathway before it is implemented, and 3) describe the topics when an expedited pathway is or is not permissible. The workgroup agreed that this pathway should be limited but was unable to describe all of the situations when it should be permissible. It therefore limited this pathway by requiring the Board to first pre-approve the policy section for expedited review and place limits on the amount of opposition received during public comment.

Under the proposed changes, any proposal being considered for an expedited review would have to first follow the normal policy development process and the policy language would have to specify that future updates would be eligible for an expedited review. The Committee is also recommending an additional measure that allows a certain number of objections to make the proposal ineligible for the expedited process. Furthermore, if the proposal receives any objections but not the number required to make it ineligible for the expedited process, the sponsoring Committee must get approval from the Executive Committee or the Board to proceed with the change.

See Summary and Goals of the Proposal above for the detailed process steps.

In developing this change, the Committee discussed how to determine whether a proposal is controversial and decided that the community would determine this through the public comment process. The Committee achieved this by establishing an appropriate number of objections that would cause the proposal to be removed from the expedited process. They chose the number of objections from specific groups by examining data on public comments from the past several years and determining the average number of opposing comments for each.

UNOS staff presented data showing that the average Board proposal receives 90% approval from Board members. This led the Committee to choose a 10% threshold (4) for the number of Board members that could object to the proposal and it would be considered too controversial for the expedited process. The Committee took a similar approach with the number of members of the public (5) who could object to the proposal, reviewing the average number of individual opposing comments on proposals in the last five years.

For individual and Board objections, the Committee decided to specify a fixed number over a percentage. This is due to the fact that it would not be easy to determine whether the threshold percentage had been met until the public comment process was complete. For example, if a 10% threshold was specified, UNOS staff would not know the total number of comments until the public comment process closed and therefore could not calculate 10% of the number until there was a total number of comments. If the proposal reached the required number of objections early in the

public comment process, the Committee wanted the proposal removed from the expedited path as quickly as possible.

The Committee also decided that a proposal should not be eligible for the expedited process if another OPTN committee (by a majority of voting members) opposed the proposal. There was consideration for specifically mentioning professional transplant society objections but, due to some difficult logistical issues associated with this, it was determined that any transplant society opposed to a policy proposal would likely be able to obtain four signatures to meet the individual threshold. In addition, there is already a process in place for transplant societies to request a separate review of proposed policies.

To be clear, the expedited process is only intended for policy changes that are determined to be non-controversial to the transplant community. The proposal will allow the Board to act in a more expedient manner when the transplant community identifies a need for routine and non-controversial changes.

Other Solutions

The above solutions are the only actions taken by the Executive Committee that propose to change the OPTN Bylaws and, therefore, require public comment. However, the Executive Committee identified other improvements worth noting to the community.

The Executive Committee is concerned with the fact that the length of the OPTN policy development process has grown significantly over the last 5-7 years. This has resulted in an increase in the amount of time it takes for the Board to respond to needed policy changes. For example, UNOS staff estimates that it took approximately 90-104 days from the start of a proposal to Board approval from 2001-2005. By 2014, it was 243-291 days. A similar trend can be seen in the length of the public comment period and from the end of the public comment period to Board approval.

The Committee determined that there are multiple reasons for the increase in the length of the process. One of the main reasons identified is that the OPTN policy development calendar does not strategically line up with the Board meetings. For example, the two main public comment periods are not scheduled in advance of the Board meeting, with time between for a committee to make final recommendations for approval. One public comment period even overlaps a Board of Directors meeting. And, the Board meetings are not scheduled with enough time in between to complete a full public comment cycle. This means that a committee cannot distribute a proposal for public comment and present a final recommendation to the Board at their next meeting. Instead, they must wait for an additional 5 or more months after the public comment period has closed to present the final proposal to the Board.

The Committee directed UNOS staff to develop a new policy development calendar that allows for a six month period between each Board meeting and schedule the two annual public comment periods and internal review processes around the Board schedule. Beginning in January 2015, this new calendar will be operationalized.

Supporting Evidence and/or Modeling:

UNOS Staff and the workgroup cataloged and reviewed the policy development calendars from 2001-2014. The review validated the perceived problem and focused the workgroup as they reviewed potential solutions (Exhibit A).

In reviewing potential solutions, the workgroup reviewed policy development models used by other rulemaking bodies. The federal government and several states utilize similar pathways for emergency and noncontroversial proposals. For example, the Administrative Procedure Act contains a good cause exemption to its public comment requirements:

> Except when no hearing is required by statute, this subsection does not apply…
>
> (B)when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.

Examples of other emergency actions include:

- Code of Virginia, § 2.2-4011 (Emergency regulations; publication; exceptions).
- California Government Code, § 11346.1(b)(2)
- Federal interim Final Rules

Examples of other expedited, non-controversial actions include:

- Code of Virginia, § 2.2-4012.1 (Fast-track rulemaking process) (2014).
- Federal direct Final Rules

Administrative Conference of the United States (ACUS) Recommendation 95-4 (Procedures for Noncontroversial and Expedited Rulemaking) (60 CFR 43110 (August 18, 1995) contains several recommendations for emergency and non-controversial rulemaking pathways.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

Not applicable.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal is intended to further the OPTN strategic goal of promoting efficient management of the OPTN and, in particular, the objective to improve responsiveness of OPTN policy to a changing environment.

Plan for Evaluating the Proposal:

The Board and Executive Committee, along with UNOS staff, will assess whether the changes are having their intended effect by tracking:

- How many proposals utilize the emergency pathway
- How many proposals utilize the expedited pathway

Additional Data Collection:

No additional data collection is required under this proposal.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the Board of Directors in June 2015 and, if approved, will be effective September 1, 2015.

Compliance Monitoring:

Not applicable

Policy or Bylaw Proposal:

Article XI: Adoption of Policies

11.1 Creating and Submitting Policy Proposals

Committees develop proposals for new policies or changes to existing policies and submit them to the Board of Directors for consideration. Committees developing proposals may also request review and comment from one or more additional Committees if necessary. For more information about OPTN Committees, see of these Bylaws.

Committees analyze policy proposals using select data to measure the effect of the proposal on the transplant community. The analysis includes baseline data that reflects how current policy is performing as well as projected outcomes to estimate the impact of the policy proposal. Data, analysis, and other information requested by the Committees are provided by the OPTN Contractor and Scientific Registry of Transplant Recipients (SRTR) contractor, as specified in their contracts with the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS).

Policy proposals include a summary that provides background information to explain the purpose of the proposal and the issues that were considered in developing the proposal.

A. The Public Comment Period

The public, including the transplant community, is usually included in the OPTN policy development process through the public comment process. Proposals to change organ allocation or membership requirements require public comment. However, some policy proposals do not require public comment, including:

- ~~Proposals that require immediate action due to patient health and safety factors.~~
- Proposals that clarify or correct existing policy rather than changing the intent or adding to the policy.
- Proposals that reflect administrative or non-substantive procedural changes that do not change the intent of the policy or do not impact the operations of the transplant community.

The public comment period is usually 45 days. ~~The sponsoring Committee may set a shorter period if a proposal needs to be expedited for patient health and safety reasons, but will make every effort to set a reasonable period to receive comments.~~

Proposals issued for public comment are distributed in the following ways:

1. Posted to the OPTN website at http://optn.transplant.hrsa.gov or mailed to all OPTN members and anyone who requests to be placed on the list.
2. Provided at regional meetings of the members.
3. Provided at meetings of interested Committees.

Comments received during the public comment period will be reviewed and addressed by the sponsoring Committee. Comments received after the end of the set public comment period may be reviewed and addressed at the discretion of the Chair of the sponsoring Committee.

Based on the comments received, the Committee may make modifications to the proposal, including withdrawal of the proposal. Should the Committee choose to recommend the policy proposal to the Board, the proposal will be updated to include the public comments and the Committee's responses and then presented to the Board of Directors as a final proposal.

11.2 Submitting Policy Proposals to the Board of Directors

After the sponsoring Committee completes the policy proposal and any necessary public comment process, the Committee submits the proposal to the Board of Directors. The Board of Directors may take *any* of the following actions:

- Approve the proposal without amendment.
- Amend and then approve the proposal.
- Reject the proposal.
- Refer the proposal back to the sponsoring Committee or to other Committees for additional consideration.
- Any other action the Board decides is appropriate.

These actions may also be considered and implemented by the Executive Committee between meetings of the Board of Directors. For more information, see *Article IV: Executive Committee* of these Bylaws.

Policies approved by the Board of Directors with or without amendment and recommended as non-mandatory will be implemented as described below.

Policies approved by the Board of Directors and recommended to be enforced as mandatory policies are forwarded to the Secretary of HHS for review and comment according to the OPTN Final Rule*, section 121.4(b)(2)* at least 60 days before implementation.

11.6 Emergency Actions

Policy proposals that meet *at least one* of the following criteria may be adopted by the Board of Directors prior to public comment:

- A proposal that is necessitated by a pending statutory or regulatory change.
- A proposal that is required due to an emergent public health issue or patient safety factors.
- A proposal that is necessitated by a new medical device or technology that affects organ allocation.

Instead, the policy development process for these proposals will require *all* of the following steps:

1. The sponsoring Committee submits the proposal according to *11.2 Submitting Policy Proposals to the Board of Directors*.
2. The proposal designates a future date upon which the policy will expire, not more than 12 months beyond the policy's effective date.

3. The policy is distributed for public comment no more than 6 months after approval. This public comment period can be shorter than the normal public comment period but must be at least 30 days.

11.7 Expedited Actions

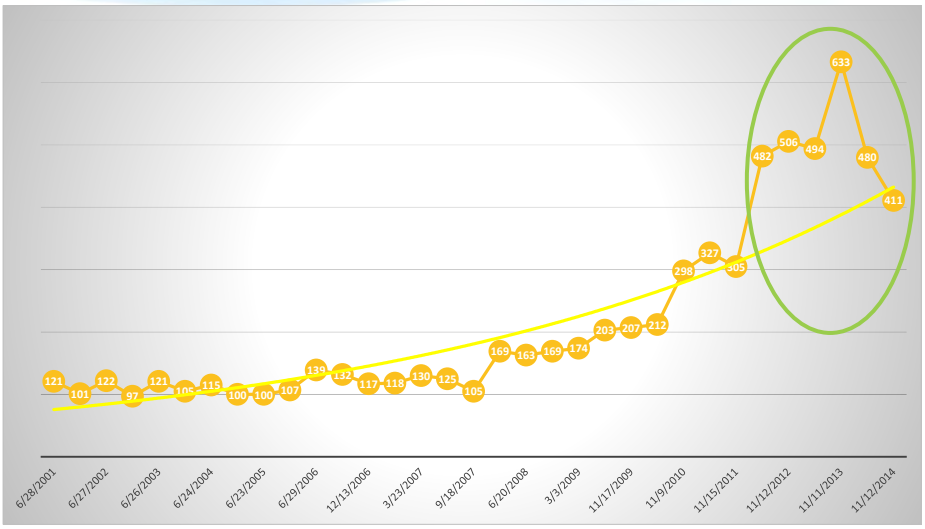
Policy proposals that are expected to be non-controversial may be adopted according to the following process:

1. The Board approves a new or revised policy that includes specific policy language defining components of the policy that will be eligible for future expedited updates as well as the anticipated frequency of updates.
2. At a later date (as directed by the policy timeline), the sponsoring Committee develops a proposal for expedited action as stipulated in the policy.
3. The proposal is distributed for public comment. This public comment period can be shorter than the normal public comment period but must be at least 30 days.
4. The sponsoring committee considers public comments and recommends final adoption of the proposal.
5. If an objection to the use of the expedited action is received during the public comment period by five members of the public, another OPTN committee, or 4 members of the Board of Directors, then the sponsoring Committee will notify the Executive Committee of the objections and proceed with the normal OPTN policy development process.
6. If the specified number of objections in #5 above are not received during the public comment period, then the process will proceed as follows:
    a. If no objections were raised during the public comment period, the proposal will become effective upon notice to the OPTN membership, unless a different date is specified.
    b. If one or more objections were raised, then the sponsoring Committee will submit the proposal for final action according to *11.2 Submitting Policy Proposals* to the Board of Directors.

~~11.6~~11.8 Developing Organ Allocation Policies

Policy proposals affecting organ allocation must specify the organ or combination of organs addressed in the policy and summarize how the proposal meets requirements of the OPTN Final Rule, *42 CFR Part 121*.

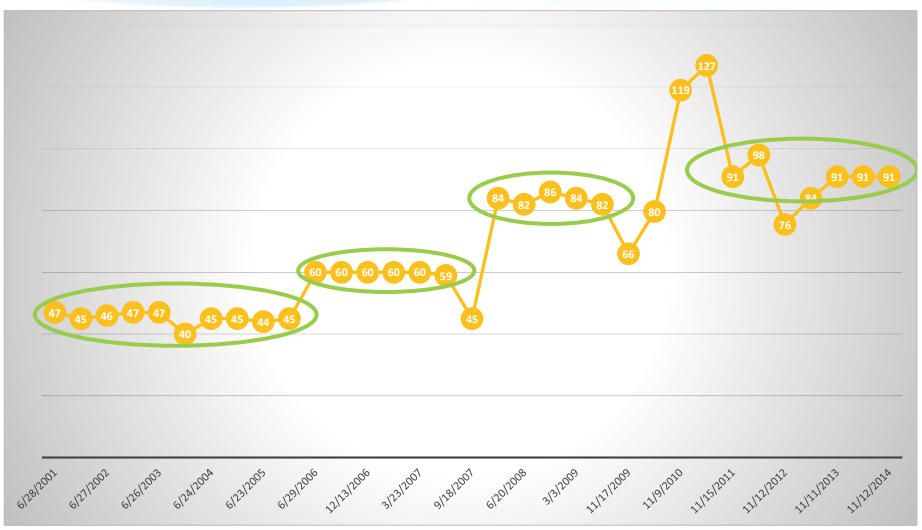
Length of Process Over Time
(from project start to BOD)



OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

Length of Process Over Time
(length of public comment)



OPTN

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

At-a-Glance

Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)

- **Affected/Proposed Bylaws and Policies:** Bylaws Appendix C.1 (Histocompatibility Laboratory Compliance); Bylaws Appendix C.2 (Facilities and Resources); Bylaws Appendix C.3 (Histocompatibility Laboratory Key Personnel); Bylaws Appendix C.4 (Laboratory Coverage Plan); Bylaws Appendix C.5 (Changes in Key Laboratory Personnel); Bylaws Appendix C.6 Histocompatibility Laboratory Policies and Procedures); Bylaws Appendix C.7 (Histocompatibility Laboratory Testing Requirements); Policy 4.2 (Requirements for Laboratory Review of Reports); Policy 4.3 (Requirements for Waiting List Data Verification).

- **OPTN/UNOS Histocompatibility Committee**

  This proposal represents the second phase of a comprehensive review of the OPTN Bylaws governing histocompatibility laboratories. This proposal contains numerous proposed changes, including a reference update to the requirement that histocompatibility laboratories maintain the standards of the American Society for Histocompatibility and Immunogenetics (ASHI) or the requirements listed in the College of American Pathologists (CAP) checklists as of a date certain, the addition of general supervisor to laboratory key personnel, modifications of education, certification, and experience requirements for laboratory key personnel, and new performance indicators that will trigger mandatory performance review of a laboratory.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  Histocompatibility testing impacts all transplant candidates. This proposal intends to ensure that histocompatibility laboratories have adequate key personnel and resources to perform high quality histocompatibility testing for the transplant programs and OPOs they serve.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal is expected to meet the OPTN Key Goals of increasing access to transplants and promoting the efficient management of the OPTN. The proposal will increase access to transplants by providing a layer of accountability in the event HLA typing errors occur and potentially reducing these typing errors in the future. To the extent that the proposal increases quality histocompatibility testing, it will also improve transplant patient safety. Furthermore, this proposal intends to rewrite the OPTN Bylaws in a manner that conveys clear membership standards for histocompatibility laboratories.

- **Specific Requests for Comment**
  None.

Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)

Affected/Proposed Bylaws: Appendix C.1 (Histocompatibility Laboratory Compliance); Appendix C.2 (Facilities and Resources); Appendix C.3 (Histocompatibility Laboratory Key Personnel); Appendix C.4 (Laboratory Coverage Plan); Appendix C.5 (Changes in Key Laboratory Personnel); Appendix C.6 Histocompatibility Laboratory Policies and Procedures); Appendix C.7 (Histocompatibility Laboratory Testing Requirements)

Histocompatibility Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

Histocompatibility laboratories ("laboratories") are a vital component to proper organ allocation, acceptance, transplantation, and post-transplant care. Laboratories perform high complexity testing that assists transplant programs and OPOs in the allocation process and carries important implications for patient safety, post-transplant care, and survival. Accordingly, the OPTN has an interest in ensuring that laboratories have adequate facilities, equipment, and resources to perform high quality histocompatibility testing.

Many of the OPTN Bylaws governing laboratories are ambiguous, fail to reflect advances in technology and current clinical practice, or are more appropriately monitored by the histocompatibility accrediting agencies (ASHI and CAP). As a result, the OPTN/UNOS Histocompatibility Committee conducted a comprehensive review of the OPTN Bylaws governing histocompatibility laboratories. The Committee determined that rewriting the Bylaws was a large project and decided to split the rewrite into two phases. In November 2013, the Committee completed and the Board of Directors approved the first phase of changes in the Bylaws. This phase included changes that required all laboratories to comply with the requirements in the documents issued by ASHI and CAP (as of a date certain), expanded the definition of changes in key personnel, and required laboratories to submit a coverage plan to the OPTN. Those changes became effective February 1, 2014. The Committee is now proposing the following additional changes:

- Adding the general supervisor to the list of laboratory key personnel.
- Creating two pathways for approval of OPTN histocompatibility laboratory directors--M.D./D.O. or earned doctoral degree. Each pathway specifies particular education, experience, and certification requirements. The Committee also proposes the addition of a foreign equivalent qualifier for both pathways (current Bylaws are silent on foreign equivalent education and experience for laboratory directors).
- Simplifying requirements for the technical supervisor, general supervisor, and clinical consultant by only requiring that these individuals meet the requirements in the federal Clinical Laboratory Improvement Amendments (CLIA).
- Eliminating references to the histocompatibility technologist, since no requirements for this position are stated in the Bylaws.
- Adding criteria for performance review of a histocompatibility laboratory, including HLA typing errors that result in an incompatible transplant or the reallocation of an organ.
- Removing sections that are out of date or more appropriately monitored by the histocompatibility accrediting agencies.

Background and Significance of the Proposal:

The OPTN Bylaws specify requirements for approval of membership in the OPTN. Histocompatibility laboratories must be approved by the Membership and Professional Standards Committee (MPSC) in order to perform testing for a transplant program or Organ Procurement Organization (OPO). A joint subcommittee comprised of members of the MPSC and the Histocompatibility Committee meet on a regular basis to review histocompatibility laboratory membership applications and requests for approval in laboratory key personnel. This joint subcommittee acts in an advisory role to the MPSC in the decision making process. In addition, the MPSC may request review of laboratories that have poor outcomes or are determined to be responsible for adverse patient safety events.

Over the past several years, it has become apparent to the Histocompatibility and Membership and Professional Standards Committees that the OPTN Bylaws governing histocompatibility laboratory membership are outdated and several key problems have been identified. Over the last two years, the Histocompatibility Committee has been conducting a comprehensive review of Appendix C and making recommended changes to the OPTN Board of Directors ('the Board'). In November 2013, the Board approved several new changes to the OPTN Bylaws governing histocompatibility laboratories pertaining to laboratory coverage. Those changes became effective February 1, 2014. The Committee has now turned its attention to the sections pertaining to the education and experience required for individuals in key laboratory personnel roles, along with performance indicators for testing performed and results reported to the OPTN. The Committee is collaborating with the American Society for Histocompatibility and Immunogenetics (ASHI) and the College for American Pathologists (CAP) on this project.

This proposal contains the following substantive changes:

- *C.1. Histocompatibility Laboratory Compliance*
  As part of the approved Bylaws rewrite phase I proposal, laboratories are required to comply with the 2012 ASHI standards or 2012 CAP checklists. The Committee proposes to update the ASHI and CAP reference date to accurately reflect the most recent versions (2013 ASHI Standards and 2014 CAP checklists). The Committee decided on this update since the revisions contain no substantive changes and are not in conflict with the OPTN Bylaws.

- *C.3. Histocompatibility Laboratory Key Personnel*
  The Committee proposes the addition of general supervisor to the list of key personnel and to modify all other relevant sections of the Bylaws (C.4 Laboratory Coverage Plan; C.5 Changes in Key Laboratory Personnel) to reflect the addition of general supervisor. The Committee reasoned it is important to consider the general supervisor position in cases where a laboratory director serves multiple laboratories and is not frequently on site to monitor testing.

  The Committee proposes simplifying requirements for the technical supervisor, general supervisor, and clinical consultant by only requiring compliance with Clinical Laboratory Improvement Amendments (CLIA) requirements. The Committee decided to remove the list of responsibilities for those positions since the list is duplicative of CLIA requirements. Additionally, the Committee proposes eliminating references to the histocompatibility technician since the Bylaws do not have requirements for this group and current Bylaw language is only definitional.

- *C.3.A. Histocompatibility Laboratory Director*
  The current OPTN Bylaws mirror the federal CLIA definition for a laboratory director even though this definition contains no requirement to have specific histocompatibility and immunogenetics experience. The OPTN only recognizes one primary laboratory director and that person directs the histocompatibility laboratory serving a transplant program or OPO. As a result, the Committee proposes a recognition of "Histocompatibility Laboratory Director" in the Bylaws. The education and experience required for the OPTN/UNOS histocompatibility laboratory director more closely mirrors what is required for the CLIA technical supervisor. This proposal would make the labels different between CLIA and the OPTN Bylaws, but there are no practical implications for individuals in these positions due to this change.

  The Committee agreed on modifications that clarify two pathways for approval of laboratory directors- M.D./D.O. or through an earned doctoral degree. The changes in this section are meant to address several different problems identified by the Committee.

  Within each pathway (which specifies the education, experience, and certification requirements that OPTN/UNOS histocompatibility laboratory directors must meet) the Committee has added language recognizing foreign equivalent education and experience. The current Bylaws are silent on the issue and this has led to qualified individuals not being approved as OPTN/UNOS histocompatibility laboratory directors. The Membership and Professional Standards Committee (MPSC), in consultation with the OPTN histocompatibility accrediting agencies (the American Society for Histocompatibility and Immunogenetics or ASHI and the College of American Pathologists or CAP), will make a final determination about whether the experience is considered equivalent to individuals in the United States. This process will mirror the process followed for determining foreign equivalent education and experience for primary transplant physicians and surgeons.

  The Committee was concerned that the current requirement that individuals with an M.D. or D.O. have a license to practice medicine in the state where the laboratory is located prevents qualified individuals from becoming histocompatibility laboratory directors, even if they have the appropriate experience and credentials in histocompatibility and immunogenetics. The Committee recognized that this is a requirement in the federal CLIA regulations, but those regulations also allow for an earned doctoral degree pathway that the current OPTN/UNOS Bylaws do not. Therefore, the Committee is proposing that individuals with an M.D. or D.O. that do not have a license to practice medicine in the state where the laboratory is located have the opportunity to qualify through the earned doctoral degree pathway.

  The Committee presented these recommendations to the American Society for Histocompatibility and Immunogenetics (ASHI) Board of Directors prior to releasing them for public comment. Several members of the ASHI Board requested that the Committee consider amending the proposal to allow for certain pre-doctoral experience to qualify for laboratory directors. This request was intended to capture individuals who have extensive pre-doctoral experience in the laboratory (for example, a general supervisor) and should have the opportunity to have that experience recognized if being considered for the laboratory director position. The Committee agreed and is proposing that appropriate pre-doctoral experience qualify. In addition, members of the ASHI Board were concerned that the laboratory director qualification requiring certification in pathology under the M.D./D.O. pathway was too limiting and suggested the inclusion of additional medical specialties. ASHI Board members were concerned because many of the other medical specialties do

not have expertise in laboratory medicine or clinical pathology, and anatomical pathology by itself is not adequate preparation. The Committee agreed and proposes certification in "anatomic and clinical or clinical pathology." The Committee further indicates medical specialty concerns are adequately addressed pursuant to the second, earned doctoral degree, pathway.

The Committee also proposes that individuals who have not served as a laboratory director or clinical consultant at an OPTN laboratory in the five years prior to the date of application submit additional documentation for the MPSC to consider in the approval process. This is to address the concern that these individuals may not have appropriate experience in the latest histocompatibility technologies and techniques.

- *C.6. Histocompatibility Laboratory Policies and Procedures*
  The Committee is proposing additional performance criteria for mandatory reviews of histocompatibility laboratories, most significantly review of laboratories that make HLA typing errors that result in an incompatible transplant or re-allocation of an organ to an individual other than the intended recipient. The Committee reviews quarterly HLA typing discrepancies flagged on match runs and donor and recipient histocompatibility forms. The data suggests that these allocation errors do occur, although they are rare. If such an error is discovered during the quarterly review, the Committee will refer the error to the MPSC for further investigation. The MPSC will make the final determination of what action is most appropriate.

  In addition to this change, the section specifying requirements for proficiency testing was reorganized for clarity and to accurately reflect histocompatibility accrediting agency requirements. No substantive changes are being proposed to proficiency testing requirements.

- *C.7. Histocompatibility Laboratory Testing Requirements*
  The Committee recommends deleting a number of sections because they are either out of date or more appropriately monitored by the histocompatibility accrediting agencies. However, the Committee intends to move Waitlist Data Verification and language on reviewing reports from Bylaws to OPTN Policy 4.2 (Requirements for Laboratory Review of Reports) and 4.3 (Requirements for Waiting List Data Verification). These requirements have not changed.

  The Committee restructured sections that pertain to submission requirements for laboratories using new techniques by drafting language that more closely mirrors ASHI requirements and requires a laboratory director review of twenty cases.

These substantive changes are accompanied with further changes that are characterized as either stylistic, noncontroversial, or to improve the Bylaws readability.

Expected Impact on Living Donors or Living Donation:

Living donors are typed by histocompatibility laboratories and crossmatches are performed for both deceased and living donor transplants; therefore, this proposal has the potential to affect living donor organs.

Expected Impact on Specific Patient Populations:

Histocompatibility testing is important for all organ transplant candidates. To the extent that this proposal improves accuracy in HLA typing, it will particularly benefit sensitized patients.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal will further the OPTN Goals of promoting transplant safety and efficient management of the OPTN. The proposal will promote transplant safety by requiring histocompatibility laboratories to accurately determine and report HLA typing, resolve HLA typing discrepancies in a timely manner, and provide a layer of accountability by DEQ and MPSC review. The proposal promotes the efficient management of the OPTN by clarifying Bylaws governing histocompatibility and eliminating Bylaws that are outdated or adequately addressed by the histocompatibility accrediting agencies. The proposal will increase access to transplants by providing a layer of accountability in the event HLA typing errors occur and potentially reducing these typing errors in the future.

Plan for Evaluating the Proposal:

The Bylaw requirement is intended to work in conjunction with Policy 4.2 which requires the Histocompatibility Committee to review at least every three months, any outstanding discrepant typing recorded since the last review. This review includes detailed discrepancies on HLA used for match runs.

The Histocompatibility Committee will evaluate this proposal 1 and 2 years post implementation by comparing percentage of HLA discrepancies prior and post implementation. The Committee's hypothesis is that increased quality of histocompatibility testing will result in decreased percentages of HLA discrepancies.

Additional Data Collection:

The addition of general supervisor position to the list of key personnel will result in the following additional data collection:

- The OPTN Contractor will send an initial survey to collect information on the individual who will be named the primary general supervisor.
- Data collection will occur anytime a new laboratory applies or there is a change in primary general supervisor.

These data will be collected to determine if the laboratories are complying with the requirements of Membership.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and will go into effect on September 1, 2015. The addition of general supervisor(s) as key personnel will require IT programming; therefore, the implementation of that section will be delayed until programming is complete.

Communication and Education Plan:

The following communication and education activities will help notify members of the clarified Bylaws language:

- Policy notice
- Presentation at Regional Meetings

Compliance Monitoring:

The OPTN Contractor will perform the following:

- Conduct a survey of all histocompatibility laboratories to verify which individuals in their laboratory meet the new definition of primary general supervisor
- Monitor the occurrence of HLA typing discrepancies

Policy or Bylaw Proposal:

Appendix C: Membership Requirements for Histocompatibility Laboratories

C.1 Histocompatibility Laboratory Compliance

Each histocompatibility laboratory member must comply with all of the following:

1. All application provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273 et seq.
2. All application provisions of the OPTN Final Rule, 42 CFR Part 121
3. The OPTN Charter
4. All OPTN Bylaws and Policies
5. The requirements in the Clinical Laboratory Improvement Amendments (CLIA) at 42 CFR § 493.1278, unless exempt
6. The requirements, as they apply to solid organ and islet transplantation, of the American Society for Histocompatibility and Immunogenetics (ASHI) ~~2012~~ 2013 Revised Standards for Accredited Laboratories, or the College of American Pathologists (CAP) Histocompatibility Checklist, Laboratory General Checklist, Flow Cytometry Checklist, and Team Leader Assessment of Director and Quality Checklist as of ~~September 25, 2012~~ April 21, 2014. This requirement does not mandate membership in either ASHI or CAP.

C.2 Facilities and Resources

Histocompatibility laboratories must have considerable facilities, equipment, and resources to ensure accurate, reliable and efficient testing.

A. Facilities

The laboratory must have:

1. Enough space and equipment so that procedures and tests can be performed accurately and efficiently.
2. Adequate facilities to store medical and test records for candidates, recipients, and donors.

B. Records Access

Records for active candidates must be immediately accessible onsite. Records for recipients and donors must be accessible as necessary to meet the clinical practice needs of any associated transplant hospital or OPO.

C. Transplant Program Affiliation

Histocompatibility laboratories must have written agreements with every transplant program the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and transplant programs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.
3. A process for requesting extended HLA typing.
4. A process for reporting and verifying HLA and unacceptable antigen data at the time of registration on the waiting list and any time there are changes.
5. A process for reporting HLA typing results to the OPTN Contractor.
6. A process for resolving HLA typing discrepancies and errors.
7. The maximum turnaround time from receipt of sample to reporting of results to the transplant program.
8. A process to obtain sensitization history for each patient.
9. The frequency of periodic sample collection.
10. The frequency of antibody screenings.
11. The criteria for crossmatching.
12. The assay format that will be used for antibody screening and for crossmatching.
13. The criteria for determining unacceptable antigens used during organ allocation.
14. The duration for which specimens need to be stored for repeat or future testing.
15. If desensitization is performed, then a protocol for monitoring antibody levels.

16. If the laboratory registers candidates for the transplant program, then a process for blood type verification according to ~~*Policy 3.1.4: Waiting List*~~ *Policy 3.3: Candidate Blood Type Determination and Reporting before Waiting List Registration*.
17. If post-transplant monitoring is performed, then a protocol for monitoring antibody levels.

D. OPO Affiliation

Histocompatibility laboratories must have written agreements with every OPO member the laboratory serves, unless clinical urgency prevents such an agreement. Written agreements between histocompatibility laboratories and OPOs must include *all* of the following:

1. The sample requirements for typing and crossmatching.
2. The loci and level of resolution typed.
3. A process for requesting extended HLA typing.
4. A process for reporting HLA typing results to the OPTN Contractor.
5. A process for resolving HLA typing discrepancies and errors.
6. The maximum turnaround time from receipt of donor sample to reporting of results to the OPO.
7. A process for prioritizing donors for histocompatibility testing.
8. The length of time for which donor specimens are required to be stored for repeat or future testing.
9. If the OPO performs crossmatching, then all methods used for crossmatching and the interpretation and reporting of the results.

C.3 Histocompatibility Laboratory Key Personnel

The laboratory must employ a histocompatibility laboratory director, a technical supervisor, a general supervisor, and a clinical consultant. One person may fill one or more positions.

The size and training of the histocompatibility laboratory staff must be enough to carry out the volume and variety of tests required to ensure accuracy and prompt completion of tests. All personnel must be licensed or meet the standards required by federal, state and local regulations.

If the laboratory provides histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas transplants, then the laboratory must have personnel for the required histocompatibility testing available 24 hours a day, seven days a week.

A. Histocompatibility Laboratory Director

The histocompatibility laboratory director ensures that the laboratory provides high quality and comprehensive histocompatibility and immunogenetics testing.

Laboratory Director Qualifications

The histocompatibility laboratory director must meet *all* of the ~~following~~ requirements~~:~~ for at least *one* of the following pathways:

1. Pathway 1 :
    - Have an M.D. or D.O. from an accredited institution, or equivalent degree from another country
    - Have a license to practice medicine in the state where the laboratory is located
    - Be certified in anatomic and clinical or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possess qualifications of those equivalent to those required for such certification
    - Have at least two years full-time experience directing or supervising clinical histocompatibility testing for solid organ transplantation
2. Pathway 2:
    - Have a doctoral degree in a medical, chemical, physical, biological, or clinical laboratory science from an accredited institution, or equivalent degree from another country
    - Be certified as a Diplomate by the American Board of Histocompatibility and Immunogenetics, a high complexity laboratory director by the American Board of Bioanalysis, or a Diplomate by the American Board of Medical Laboratory Immunology
    - Have at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics, and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation

    The MPSC will review, in consultation with the histocompatibility accrediting agencies, the credentials of professionals with foreign education or training and determine whether the foreign education or training is equivalent to that obtained in the United States.

~~1. The director must be an M.D., D.O., or Ph.D. in science, and must meet the qualifications of a director of high complexity testing according to federal CLIA requirements defined in *42CFR §493.1441*. An M.D. or D.O. must also~~

~~have a license to practice medicine in the state where the laboratory is located.~~

2. ~~The director must have at least two years training or experience in histocompatibility testing in an OPTN approved training program or three years experience under an OPTN histocompatibility laboratory director.~~

~~Laboratory Director Candidate Requirements~~

Any professional being considered for the position of histocompatibility laboratory director who has not served in the role of laboratory director or clinical consultant at an approved OPTN histocompatibility laboratory within five years prior to the date of application must also provide ~~*one*~~ *all* of the following:

- ~~Proof of certification by the American Board of Histocompatibility and Immunogenetics.~~
- A portfolio of 50 cases, covered during the five years prior to the date of application, that demonstrates the professional's analytical skills, ability to recognize and resolve testing and interpretation issues, and instances when the applicant made recommendations for additional testing or clinical care.
- Proof of active ~~laboratory~~ interaction with transplant professionals.
- A letter from the applicant that describes all experience in immunology and clinical histocompatibility testing, including ~~A~~ a summary of time spent in the laboratory, technologies used, level of responsibility, and specific tasks performed.
- A current curriculum vitae or resume.
- Demonstrated ~~knowledge of the fundamentals of immunology, genetics, and histocompatibility testing and this knowledge should be reflected by~~ participation in transplant or clinical laboratory professional conferences and publications in peer-reviewed journals. ~~An American Board of Histocompatibility and Immunogenetics Diplomat (ABHI D) certification is highly recommended.~~

3. ~~If a portfolio is submitted, the portfolio may be also reviewed by an OPTN approved accrediting agency as part of their application process. The portfolio must include:~~

    1. ~~A log of 50 cases reviewed in each histocompatibility testing technique used in organ transplantation. Each case should include the date and a record identification number, along with a brief description and the testing technology used. A minimum of ten of these cases must include all the related worksheets and notes.~~

2. ~~Cases that demonstrate the applicant's analytical skills, including the ability to recognize and resolve difficult testing and interpretation issues. These cases should also include instances when the applicant made recommendations for additional testing or clinical care.~~

~~In addition, laboratories must submit the following items as part of the application:~~

All documentation that verifies training and experience must be sent directly to the OPTN Contractor from all directors of histocompatibility laboratories where the training was obtained.

~~**Laboratory Director Responsibilities**~~

~~A histocompatibility laboratory director has the following responsibilities:~~

~~1. Ensure that the laboratory facilities are adequate and safe from physical, chemical, and biological hazards.~~
~~2. Provide consultation to clients on test results.~~
3. ~~Be available to provide onsite, telephone or electronic consultation, as needed~~.
~~4. Ensure that an approved procedure manual is available to all technical personnel.~~
~~5. Supervise personnel to ensure that all duties are properly performed.~~
~~6. Ensure that a qualified General Supervisor is on-site for all testing.~~
~~7. Ensure that there are current job descriptions and task assignments for all personnel.~~
~~8. Ensure that the performance of personnel is evaluated and documented at least semi-annually during the first year, and annually after that.~~
~~9. Be available to all staff members to address issues of concern.~~
~~10. Ensure that test systems provide quality results.~~
~~11. Ensure that the laboratory enrolls in appropriate proficiency testing programs.~~
~~12. Ensure that the laboratory has quality control and quality assurance programs.~~
~~13. Ensure that corrective action is taken if test systems deviate from performance specifications.~~
~~14. Ensure all required information is included on test reports.~~
~~15. Employ enough staff with appropriate training and experience.~~

B. Technical Supervisor Qualifications ~~and Responsibilities~~

The technical supervisor must meet all the qualifications and fulfill the responsibilities for laboratory director ~~as~~ ~~outlined~~ ~~in~~ according to *C.3.A. Laboratory Director* above and for technical supervisor ~~as specified in~~ according to *42 CFR 493*. ~~In addition, the supervisor must have at least two years of~~

~~training in an OPTN approved training program or three years experience under a qualified OPTN histocompatibility laboratory director.~~

~~A technical supervisor has the following responsibilities:~~

1. ~~Select appropriate test methodologies.~~
2. ~~Establish performance criteria, validation, and quality control for all tests.~~
3. ~~Ensure proficiency testing is performed properly and reviewed with staff.~~
4. ~~Ensure that technical problems are resolved and corrective action is taken when appropriate.~~
5. ~~Ensure that test reports are issued only when test systems are functioning properly.~~
6. ~~Identify training needs and provide in-service training as needed.~~
7. ~~Evaluate staff competency and performance.~~

C. General Supervisor

A general supervisor must meet the qualifications for a general supervisor as defined by ~~Clinical Laboratory Improvement Amendments (CLIA)~~ *42 CFR 493* and have at least three years experience in human histocompatibility or transplant immunology testing under the supervision of a qualified histocompatibility laboratory director or technical supervisor.

~~A general supervisor must have *one* of the following:~~

- ~~A bachelor's degree and at least three years experience in human histocompatibility or transplant immunology testing under the supervision of a qualified director or technical supervisor.~~
- ~~A related associate's degree or certificate, as required by CLIA, and five years of supervised experience if a bachelor's degree has not been earned. A Certified Histocompatibility Specialist (CHS-ABHI) certification is strongly recommended.~~

D. Histocompatibility Technologist Qualifications

A histocompatibility technologist must meet the qualifications for a histocompatibility technologist as defined by ~~CLIA~~ 42 CFR 493 and must have had one year of supervised experience in human histocompatibility or transplantation immunology testing, regardless of academic degree or other training and experience. ~~Either CHS-ABHI or Certified Histocompatibility Technologist (CHT-ABHI) certification is strongly recommended.~~

~~E. Histocompatibility Technician Qualifications~~

~~The term histocompatibility technician is applied to trainees and other laboratory personnel with less than one year's supervised experience in human histocompatibility or transplantation immunology testing, regardless of academic degree or other training and experience.~~

~~F~~E. Clinical Consultant Qualifications ~~and Responsibilities~~

The clinical consultant must meet all the qualifications for laboratory director as outlined in *C.3.A. Laboratory Director* above and for clinical consultant as specified in *42 CFR 493.* ~~A qualified clinical consultant must be available to consult with and provide opinions about the appropriateness of histocompatibility or transplantation immunology tests ordered. The clinical consultant will interpret test results in consideration of patient diagnosis and management. Required qualifications are described in detail in the final version of the CLIA Regulations.~~

~~The clinical consultant must be an M.D., D.O. or Ph.D. in science. An M.D. or D.O. must also have a license to practice medicine in the state where the laboratory is located. A Ph.D. must be board-certified by an accrediting agency accepted by the U.S. Department of Health and Human Services (HHS). The clinical consultant must also have experience in clinical transplantation.~~

~~A histocompatibility laboratory clinical consultant has the following responsibilities:~~

~~1. Ensure that test reports include all information required for test interpretation.~~
~~2. Ensure that consultation is available at all times to evaluate patient and donor compatibility for organ transplantation and that availability is communicated with laboratory clients.~~
~~3. Assist clients in test selection.~~
~~4. Assist clients in the interpretation of reported test results.~~
~~5. Report assessed risks associated with the degree and specificity of allosensitization and crossmatch results.~~

~~G~~F. Competency Testing and Continuing Education of Staff

The laboratory must test its staff for competency in performing test procedures. The testing must be done annually, and must be completed for each type of test the staff performs.

The director, technical supervisor, and all technical staff must participate in continuing education in histocompatibility, immunogenetics or clinical transplantation as required for accreditation by national, state, and local regulatory agencies.

C.4 Laboratory Coverage Plan

The histocompatibility laboratory director, in conjunction with the technical supervisor, general supervisor, and clinical consultant, must submit a detailed Laboratory Coverage Plan to the OPTN Contractor. The Laboratory Coverage Plan must describe how continuous coverage is provided by laboratory personnel.

The Laboratory Coverage Plan must address *all* of the following:

1. The laboratory must document that qualified key personnel are providing coverage at all times, including during the entire application process for changes in key personnel, regardless of the status of the application.

2. The laboratory must document that the laboratory director, technical supervisor, general supervisor, and clinical consultant are available to provide onsite, telephone, or electronic consultation to facilitate organ acceptance and transplantation.

3. The laboratory must document if any of the responsibilities designated to the laboratory director, technical supervisor, or clinical consultant will be performed by other laboratory staff. This documentation must include a list of the duties delegated, the times when the duties will be delegated, the qualifications of the staff that will perform the delegated duties, and the quality systems in place to ensure the duties are correctly performed.

4. If the laboratory is engaged in histocompatibility testing for deceased kidney, kidney-pancreas, or pancreas donor transplants, then the laboratory must document that key personnel and qualified testing personnel are available 24 hours a day, 7 days a week to provide laboratory coverage, unless a written explanation is provided that justifies the current level of coverage to the satisfaction of the MPSC.

5. If any key personnel serves more than one histocompatibility laboratory, then the Laboratory Coverage Plan must specify how continuous coverage will be provided at each histocompatibility laboratory served.

C.5 Changes in Key Laboratory Personnel

A. Change in Laboratory Director, Technical Supervisor, General Supervisor, or Clinical Consultant

When the histocompatibility laboratory is informed that the laboratory director, technical supervisor, general supervisor, or clinical consultant plans to leave or otherwise ends active participation in the laboratory, the laboratory must:

1. Notify the OPTN Contractor in writing within seven business days of when the laboratory becomes aware of the change in key personnel.

2. Submit a completed Personnel Change Application to the OPTN Contractor no less than 30 days before the end of the individual's active employment or change in status. The Personnel Change Application must document that the new or acting laboratory director, technical supervisor, clinical consultant, and general supervisor meet the requirements of these Bylaws.

3. Submit an updated Laboratory Coverage Plan no less than 30 days before the date of departure that specifies how continuous coverage will be provided at the laboratory by all key personnel during and after the transition period to a new or acting laboratory director, technical supervisor, or clinical consultant.

4. If the histocompatibility laboratory receives less than 60 days notice of the key personnel change, then the laboratory must submit a completed Personnel Change Application and updated Laboratory Coverage Plan to the OPTN Contractor within 30 days of the date of departure.

A change in key personnel can be any of the following:

1. Departure of the director, technical supervisor, general supervisor, or clinical consultant.

2. Any key personnel unavailable to perform responsibilities for more than 30 days.

3. Reinstatement of the previously designated laboratory director, technical supervisor, general supervisor, or clinical consultant.

4. Any key personnel that accepts additional responsibilities for more than 30 days at another histocompatibility laboratory.

B. Failure to Notify the OPTN Contractor of Key Personnel Changes

Any histocompatibility laboratory that fails to inform the OPTN Contractor of a change in the laboratory director, technical supervisor, general supervisor, or clinical consultant or to submit the required Personnel Change Application within the periods specified above will be reviewed by the MPSC. The MPSC may impose a sanction, including, but not limited to, any of the following:

1. Notice of Uncontested Violation

2. Letter of Warning

3. Letter of Reprimand

Failure to inform the OPTN Contractor of changes in key personnel or to submit the required Personnel Change Application will result in a recommendation that the

Board of Directors take appropriate adverse actions. Additionally, the Board of Directors may notify the Secretary of Health and Human Services (HHS) of the violation.

C.6 Histocompatibility Laboratory Policies and Procedures

~~The overall performance of a laboratory is the best indication of the quality of leadership, technical supervision, and clinical consultation being provided. The sections below describe the areas that are monitored and assessed by the OPTN Histocompatibility Committee or the accrediting agencies approved by the OPTN Contractor, and are used to measure the laboratory's performance.~~

A. Criteria for ~~Mandatory~~ Performance Review of ~~Director, Technical Supervisor or Clinical Consultant~~ a Histocompatibility Laboratory

The OPTN Contractor may review a histocompatibility laboratory if at any time it has *any* of the following performance indicators:

- Failure to comply with the requirements and regulations according to C.1. *Histocompatibility Laboratory Compliance*.
- Any of the following performance indicators on external proficiency testing:
  1. Less than 100% ~~successful~~ satisfactory performance in an ABO external proficiency testing program.
  2. For programs other than ABO, a less than 80% ~~successful~~ satisfactory performance in an external histocompatibility proficiency testing program within ~~a year~~ the previous twelve months.
- Accreditation revoked by any OPTN approved histocompatibility regulatory agency.
- A focused re-inspection by any OPTN approved histocompatibility regulatory agency.
- Restrictions imposed on the laboratory by any OPTN approved histocompatibility regulatory agency.
- One or more HLA typing or reporting errors on a deceased or living donor that results or could result in an incompatible transplant or the re-allocation of an organ to someone other than the intended recipient.

~~A histocompatibility laboratory will also be reviewed if it has *two or more* of the following performance indicators annually:~~

- ~~Error rates not within acceptable limits as defined by the laboratory quality assurance program.~~
- ~~Test completion times that are not within acceptable limits as defined by the laboratory quality assurance program.~~

- ~~Incomplete or missing proof of training, continuing education, and competency evaluations for all personnel as required by the OPTN Contractor.~~
- ~~Incomplete or missing records of all continuing education for testing staff, director, technical supervisor or clinical consultant.~~
- ~~Incomplete or missing documentation of annual director review of training and competency evaluation for all testing staff.~~
- Unresolved or repeat ~~D~~deficiencies identified during inspections conducted by OPTN approved regulatory agencies that are in violation of OPTN Contractor standards. When deficiencies are cited, laboratories must document that the deficiencies have been corrected.
- Complaints from transplant programs, OPOs, or other clients that have not been documented, investigated and resolved.
- Incomplete submission of all OPTN Contractor forms or forms not submitted within the 180 day time limit.
- ~~Significant discrepancies in deceased donor HLA typing results.~~

B. Information Required from Laboratories with Unsatisfactory Performance

The OPTN Contractor may request at any time from a histocompatibility laboratory with unsatisfactory performance *any* of the following:

- Letters from the affiliated transplant program ~~physicians or coordinators~~ or OPO staff describing the level of interaction and involvement of the director, technical supervisor and clinical consultant.
- Interviews with transplant program or OPO staff.
- Laboratory complaint log and documentation of resolutions from other healthcare professionals.
- Samples of laboratory reports that demonstrate the review of patient history, notation of unusual results, and recommendations for additional testing.
- Documentation of any professional extracurricular commitments, including estimates of time required, for laboratory director, technical supervisor, general supervisor, ~~consultant~~ and clinical consultant outside of the histocompatibility laboratory. ~~This may include other employment, current committee assignments, teaching commitments, students mentored, research commitments, grants, and all other patient care responsibilities.~~
- Quality Assessment and Performance Improvement records.
- Other material as requested.

C. Periodic Reviews

In order to determine compliance with the ~~OPTN Final Rule, *42 CFR Part 121*, these Bylaws, and OPTN Policy~~ requirements and regulations according to *C.1. Histocompatibility Laboratory Compliance*, histocompatibility laboratory members will be reviewed, including on-site reviews, and must fulfill any requests for information from the OPTN Contractor. Failure to comply with these rules and requirements will be cause for corrective action as described in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

D. Regulatory Agency Adverse Actions

If any regulatory agency takes a final adverse action against a histocompatibility laboratory, the laboratory must notify the OPTN Contractor within 10 business days. The histocompatibility laboratory must also provide any documents relating to the final adverse action to the OPTN Contractor, along with the final determination of the regulatory agency.

E. Inactive Status

A histocompatibility laboratory that is voluntarily inactive, declared inactive or withdraws from membership will be ineligible and may not provide histocompatibility testing to any OPTN members.

C.7 Histocompatibility Laboratory Testing Requirements

~~The laboratory must perform tests only at the written or electronic request of an authorized person. The laboratory must ensure that the request includes:~~

~~1. The test subject's name or other unique identifier.~~
~~2. The name and address or other identification of the person who ordered the test.~~
~~3. Date of specimen collection.~~
~~4. Time of specimen collection, if significant to the test.~~
~~5. Tests ordered.~~

~~Oral requests for laboratory tests are permitted only if the laboratory obtains written authorization for testing within 30 days of the request.~~

~~A. Handling of Specimens~~

~~Histocompatibility laboratories must have available and follow written policies and procedures for specimen collection. Laboratories must follow these guidelines when handling and processing specimens for testing:~~

~~1. Each blood or tissue sample submitted for testing must be individually labeled with the name or other unique identification number for the individual and the date of collection.~~

2. The laboratory must maintain a system to ensure reliable specimen identification throughout collection, processing, testing and reporting. The laboratory must have criteria for specimen rejection and a process to ensure that rejected specimens are not tested.
3. If the laboratory draws blood samples, it must use a procedure that ensures minimal possibility of infection of the donor and contamination of the sample. All needles and syringes must be disposable.
4. Laboratory personnel must handle and transport all blood and tissue samples as though they could transmit infectious diseases.
5. The laboratory must confirm and document that anticoagulant and preservation solutions do not interfere with test performance. The anticoagulant or preservation solutions used must preserve the specimen integrity for the length of time and under the storage conditions the laboratory procedures require between sample collection and testing.

B. Handling of Reagents

The laboratory must properly label and store all reagents according to manufacturer's instructions or regulatory agency requirements to maintain optimal reactivity and specificity. Any deviation from a manufacturer's instructions for storage or any local storage guidelines must be explained by the laboratory.

Reagents, solutions, culture media, controls, calibrators, and other supplies must be labeled to indicate:

1. Identity including titer, strength or concentration.
2. Recommended storage requirements.
3. Preparation and expiration date, if any.

Laboratories must have a policy for quality control of each shipment and lot of reagents, and must adhere to the policy. Laboratories must ensure that:

1. Reagents from different lots of commercial kits are not mixed.
2. A process is in place to document the lot of reagents used in tests.
3. Each new shipment and lot of reagent is tested for quality and performance before test results using these reagents are reported.

C. Testing Standards

Laboratories must meet requirements for testing accuracy and completeness as established by the OPTN Board of Directors through the OPTN Contractor policy development process. These standards are established to ensure accurate and dependable histocompatibility testing consistent with current technology and the availability of reagents. These testing standards establish minimal criteria that all histocompatibility laboratories must meet.

The following testing standards have been prepared by the Histocompatibility Committee, and approved by the OPTN Board of Directors:

1. All procedures used in histocompatibility testing must conform to established protocols and be independently validated by the laboratory prior to use for clinical testing.
2. Each procedure must include quality assurance measures to monitor test performance.
3. Laboratories using its approval by the OPTN Contractor as proof of compliance to these standards must be current OPTN members.

The laboratory must perform at least twice a year a side-by-side comparison of any test results if it:

1. Performs the same test using different methods or instruments.
2. Performs the same test at multiple sites.

The laboratory must verify or establish for each testing method the performance requirements for accuracy, precision, analytical sensitivity and specificity, and the acceptable range of test results. The laboratory must have appropriate controls for each test to evaluate test performance and accuracy.

Proficiency Testing and Competency Evaluation

The laboratory must participate in at least one external proficiency testing program, if available, for each analyte to assess the laboratory's ability to accurately perform testing. If an external proficiency program is not available, the laboratory must use other procedures that meet CLIA requirements to validate performance at least semi-annually for each analyte. The laboratory must test proficiency samples in the same manner as that for testing clinical samples.

The laboratory must determine and document the cause for each unsatisfactory proficiency test result. Unsatisfactory performance can be *either* of the following:

- Less than 80 percent correct for an entire year for a specific analyte or within a single survey.
- Two out of three consecutive surveys graded as unsatisfactory.

If a laboratory's performance in an external proficiency testing program is unsatisfactory, the laboratory must participate in an enhanced proficiency testing program until given a satisfactory result.

D. Quality Assurance

Laboratories must have ongoing procedures for monitoring and evaluating its quality assurance program including procedures to evaluate corrective action taken. Laboratories must document and assess problems identified during quality assurance reviews, discuss them with the staff, and take corrective action to prevent recurrences. Ineffective policies and procedures must be revised based on the outcome of the evaluation.

Laboratories must document all quality assurance activities including problems identified and corrective action taken, for a minimum of two years or the period required by local, state, federal and OPTN regulations.

If any error or discrepancies in test results are detected, the laboratory must promptly:

1. Notify the person ordering or using the test results.
2. Issue corrected results and reports.
3. Maintain copies of both the original and the corrected report for a minimum of two years or the period required by local, state and federal regulations.

Laboratories must also have a process for addressing any discrepancies in HLA typing results for the same individual as reported by different laboratories or at different times as described in *Policy 4.4: Resolving Discrepant Donor and Recipient HLA Typing Results.*

E. Procedure Manual

All laboratory procedures must be detailed in a procedure manual that is readily available and located where the procedures are performed. Manufacturer product inserts are not acceptable in place of a written procedure.

The Laboratory Director must review the procedure manual at least annually and document this review in the manual. The Director must approve any new procedures or changes in existing procedures and record this approval in the manual by signing and dating the manual when the changes are made.

F. Records and Test Reports

The laboratory must record the following information for each test performed:

1. Test requisition.
2. Subject identification number.
3. Accession number or unique identification of the specimen.
4. The tissue source of the specimen.
5. The dates of specimen collection and receipt.

6. The time of specimen receipt, if relevant.
7. The condition and disposal of the specimens that do not meet the criteria for acceptability.
8. The records and dates for specimen testing including the staff that performed the tests.
9. The tests, the type of specimen used for testing, test data and results.
10. Copies of preliminary and final reports, including dates.
11. Documented review of these by the Director or Technical Supervisor or other staff member who meets at least the minimum requirements of General Supervisor.

The laboratory must have record storage systems that enable it to report results in a timely, accurate, reliable and confidential manner. Records may be saved in computer files provided that back-up files (either electronic or hard copies) are maintained to prevent loss of data.

The laboratory must ensure test subject confidentiality throughout the parts of the testing process that are under the laboratory's control.

All test reports must contain:

1. The name and address or other unique identifier of the laboratory or institution.
2. The date of sample collection.
3. The date of sample testing when pertinent to the interpretation of the test.
4. The name or unique identifier of each individual tested.
5. The date of the report.
6. The test results.
7. The units of measurement, if applicable.

Reports must be reviewed by the Director, or Technical Supervisor, or a staff member who meets at least the minimum requirements of a General Supervisor prior to release. All deceased donor HLA typing or crossmatch reports must be reviewed during the next day of regular laboratory operation.

Waiting List Data Verification

All histocompatibility laboratories must review and verify the waiting list histocompatibility data for every patient whose test results the laboratory completed. Documentation of such review must be kept for at least three years or the period required by local, state and federal regulations, whichever is the longer. This document must be available to the OPTN Contractor on request.

~~G.~~ ~~Service Requirements~~

~~All complaints and problems reported to any laboratory must be documented. The Laboratory must investigate complaints and take corrective action as necessary.~~

~~The laboratory must have a system in place to document problems that result from communications failures between the laboratory and the individual who orders tests or receives results.~~

~~The laboratory must, upon request, make available to clients a list of the test methods employed by the laboratory, a list of performance specifications for each method and a list of interfering factors that could affect interpretation of test results. Updates on testing information must be provided whenever changes occur that affect test results or the interpretation of test results.~~

~~H~~A. Subcontracting

~~A histocompatibility laboratory may use another laboratory as a subcontractor to perform testing.~~ If a histocompatibility laboratory refers testing to another laboratory, the subcontracting laboratory must be *both*:

1. CLIA certified ~~or~~ unless exempt under federal law.
2. OPTN-approved~~, ASHI accredited, or CAP accredited for that testing~~.

The laboratory director must review and approve all test results returned from the subcontracting laboratory before release. ~~For all testing performed by a subcontractor laboratory, the results must be returned to the referring laboratory and released only after the review and approval of the Director of the laboratory.~~ The identity of the subcontracting laboratory and that portion of the testing for which it bears responsibility must be noted in the report of the histocompatibility laboratory. A copy of the testing laboratory's report must be kept on file by the laboratory receiving the results.

~~Proficiency testing must not be referred to another laboratory.~~

~~I~~B. Submission Requirements for New Laboratories

~~A new histocompatibility laboratory is defined as one that has not yet been approved as an OPTN histocompatibility laboratory member.~~

If a laboratory seeking OPTN membership has not previously been approved as an OPTN histocompatibility laboratory member, then the laboratory must ~~New laboratories are required to~~ submit procedures and test validation data for all categories and methods of testing performed to the OPTN Contractor upon request ~~unless the testing is performed, without exception, by another approved~~

~~laboratory. These materials must be submitted~~ ~~an OPTN approved histocompatibility laboratory accrediting agency~~.

~~J~~C. Submission Requirements for Laboratories Using New Techniques

~~A new technique is defined as a major change or addition in testing methodology, including but not limited to:~~

- ~~The addition of molecular typing for class I or class II.~~
- ~~A major addition or change in the method used for molecular typing.~~
- ~~The addition of flow cytometry phenotyping or crossmatching.~~
- ~~A major addition or change in the method used for antibody identification or crossmatching.~~

Laboratories adding or changing test methods must submit *all* of the following to the OPTN Contractor:

1. P~~p~~rocedures and test validation data for the new tests and methods ~~to an OPTN approved histocompatibility laboratory accrediting agency, with a copy to the OPTN Histocompatibility Committee. The laboratory must also submit the~~

2. T~~t~~he curriculum vitae for the histocompatibility laboratory ~~D~~director documenting experience in the new testing, any related publications, and number of years of experience as the histocompatibility laboratory director of another laboratory approved for the new testing techniques

~~The curriculum vitae should include qualifications such as publications and years of experience as the Director of another laboratory approved for the new techniques.~~ A summary of the histocompatibility laboratory ~~D~~director review of ~~five~~ twenty cases for each type of test, including the testing and interpretation, may be submitted instead if the ~~d~~Director does not have documented experience in the new testing techniques.

~~The following data are required when a histocompatibility laboratory begins using a new testing technique:~~

~~1. A summary of the internal validation data and the Director's summary of that data.~~
~~2. The step-by-step procedure including worksheets and list of reagents.~~
~~3. The clinical protocol that validates the use of the procedure.~~
~~4. The program for training staff in the new testing technique.~~
~~5. Documentation of the training of staff that will be performing the test and reviewing the test results.~~

~~6. Performance requirements, including accuracy, precision, sensitivity, specificity, reportable range of test results, normal values, and any other relevant characteristics.~~
~~7. Quality control procedures.~~
~~8. Calibration data for necessary equipment.~~
~~9. Quality assurance data.~~
~~10. Evidence that the laboratory is currently enrolled in a Proficiency Testing (PT) program for the test, if available.~~
~~11. Tests results including worksheets and sample reports with interpretation of 10 samples including at least one of each of the test materials that will be used by the laboratory. Laboratories without access to a particular type of sample may request that it be supplied by another OPTN accredited laboratory. Multiple samples from the same individual may not be used.~~
~~12. Externally blinded side-by-side validation tests using specimens from an OPTN accredited laboratory, or well-characterized reference materials (ASHI repository or commercial panels) equivalent to those provided by the selected PT program, or a complete year of PT. A combination of these may also be used to meet this requirement.~~

~~Results from the reference laboratory and the validating laboratory must be reported independently.~~

OPTN Policies

4.2 Requirements for Laboratory Review of Reports

Reports must be reviewed by the laboratory director, technical supervisor, or a staff member who meets at least the minimum requirements of a general supervisor prior to release. All deceased donor HLA typing and crossmatch reports must be reviewed during the next day of regular laboratory operation.

4.3 Requirements for Waiting List Data Verification

All histocompatibility laboratories must review and verify the waiting list histocompatibility data for every patient whose test results the laboratory completed. Documentation of such review must be kept for at least three years or the period required by local, state and federal regulations, whichever is the longer. This document must be available to the OPTN Contractor on request.

4.~~2~~4 Resolving Discrepant Donor and Recipient HLA Typing Results

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

At-a-Glance

Proposal to Establish a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations

- **Affected/Proposed Policy:** Bylaws, Appendix B (Membership Requirements for Organ Procurement Organizations (OPOs)); Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs)

- **Membership and Professional Standards Committee**

  The Membership and Professional Standards Committee (MPSC) has noted that members having difficulty with compliance or performance often do not have well-developed quality assessment and performance improvement (QAPI) programs. Currently, OPTN bylaws do not require that members establish and implement a QAPI program. Motivated by this observation, the MPSC proposes modifications to OPTN Bylaws that require members to implement a QAPI program that must include certain essential elements that are outlined in the proposed Bylaws. A requirement that members develop and implement a comprehensive QAPI program should assist members in their efforts to improve performance and remain in compliance with OPTN obligations.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Quality Staff
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Transplant Hospital and Program Quality Staff

- **Number of Potential Candidates Affected**
  N/A

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal addresses the OPTN key goals of promoting transplant patient safety and improving post-transplant survival. The proposal will provide a tool to the MPSC to encourage and assist OPTN members in the development and implementation of robust QAPI programs. Robust QAPI programs resulting in process and performance improvement will advance these goals of promoting transplant patient safety and improving post-transplant survival.

- **Specific Requests for Comment**
  Should a requirement that organ procurement organizations and transplant hospitals develop and implement a Quality Assessment and Performance Improvement plan be included in the OPTN Bylaws?

Proposal to Establish a Quality Assessment and Performance Improvement Requirement for Transplant Hospitals and Organ Procurement Organizations

Affected/Proposed Policy: Bylaws, Appendix B (Membership Requirements for Organ Procurement Organizations (OPOs)); Appendix D (Membership Requirements for Transplant Hospitals and Transplant Programs)

Membership and Professional Standards Committee (MPSC)

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

The MPSC has noted that members having difficulty with compliance or performance often do not have well-developed quality assessment and performance improvement (QAPI) programs. Currently, OPTN bylaws do not require that members establish and implement a QAPI program. Motivated by this observation, the MPSC proposes modifications to OPTN Bylaws that require members to implement a QAPI program that must include certain essential elements that are outlined in the proposed Bylaws. A requirement that members develop and implement a comprehensive QAPI program should assist members in their efforts to improve performance and remain in compliance with OPTN obligations.

Background and Significance of the Proposal:

The MPSC is charged with ensuring that OPTN/UNOS members comply with the criteria for institutional membership. As part of this charge, the MPSC monitors members' compliance with OPTN obligations including reviews of member performance and compliance with policies and bylaws. Within the context of these reviews, the MPSC may request information about a member's QAPI processes and request submission of plans for performance improvement, corrective action, or quality improvement. The MPSC has found that members under review for compliance matters with significant non-compliance history often have non-existent or minimal QAPI programs. This is also true for members under review for extended periods of underperformance. In addition, a common finding by peer visit teams has been the lack of a robust QAPI program. The MPSC concluded that many of these members would have been less likely to experience a long history of underperformance or multiple compliance issues if the members had robust QAPI programs. In response to these experiences, the MPSC established a project to investigate the options for an OPTN requirement for establishment and implementation of a QAPI plan. The inclusion of a QAPI requirement in the OPTN Bylaws would provide the MPSC a basis to require a member to implement or strengthen its QAPI program and to hold members accountable where the lack of an adequate QAPI program has resulted in serious lapses in compliance or performance.

The use of quality processes is a widely accepted tool for evaluation and implementation of process and performance improvements in healthcare.[1] The transplant community has recognized the need for and has been moving towards codified and more thorough quality improvement initiatives. The Centers for Medicare and Medicaid Services (CMS) requires that transplant hospitals and organ procurement organizations have Quality Assessment and

[1] Institute of Medicine. (2001) Crossing the quality chasm: A new health system for the 21st century. National Academy Press: Washington, D.C.

Performance Improvement (QAPI) programs in place and evaluates these programs during CMS surveys.[2]

Although CMS Conditions of Participation include a QAPI requirement, the MPSC proposes a separate OPTN QAPI requirement because the MPSC cannot rely on a CMS requirement to take action. The MPSC may request information about a member's QAPI processes and ask them to submit plans for performance improvement, corrective action or quality improvement. However, the MPSC has no basis within OPTN policy or bylaws for requiring a member to implement or strengthen its QAPI program. The MPSC also cannot hold members accountable where the lack of an adequate QAPI program has resulted in a serious lapse in compliance or performance. In addition, not all transplant programs are CMS approved. Approximately 13% of transplant programs are not CMS approved, and therefore, not required to comply with CMS' Conditions of Participation. In an effort to avoid an additional burden on those CMS approved organizations, the MPSC reviewed CMS requirements while developing proposed OPTN QAPI requirements, aiming for consistency between the two organizations' QAPI requirements. The requirements of this proposal are consistent with CMS' QAPI requirements.

The MPSC strived to reach a balance between a requirement that is too detailed, thereby creating an undue burden on members; and one that would be more general, thereby failing to provide members with notice of what is expected. Through the proposed requirements, the MPSC can request that members improve a QAPI plan and implement it. If a member fails to comply, the MPSC can then take an action, if needed. In addition, an action can be taken by the MPSC if a member does not have a QAPI program or has not implemented its plan. In order to develop the least burdensome solution to the problem, and recognizing the extensive reviews of QAPI programs recently implemented by CMS, the MPSC will only review compliance with the proposed QAPI requirements in conjunction with an identified compliance or performance issue.

The proposal includes QAPI requirements for OPOs and transplant hospitals. The Committee considered requirements for histocompatibility laboratories but deferred inclusion in the proposal. The Histocompatibility Committee is currently working on a substantial rewrite of the Bylaws applicable to histocompatibility laboratories. The MPSC provided suggested language that mirrors the language in this proposal to the Histocompatibility Committee with a recommendation that a QAPI requirement be included in the rewrite of the Bylaws applicable to histocompatibility laboratories.

Expected Impact on Living Donors or Living Donation:

The requirement for the development and implementation of a QAPI plan would apply to living donor components of transplant programs.

Expected Impact on Specific Patient Populations:

This proposal will not have a disproportionate impact on any specific patient population.

[2] *Code of Federal Regulations*, Condition of Participation: Quality Assessment and Performance Improvement (QAPI), title 42, sec. 482.96; *Code of Federal Regulations*, Condition: quality assessment and performance improvement (QAPI), title 42, sec. 486.348; Catapult Consultants, LLC. *Quality Assessment and Performance Improvement (QAPI) Programs: A Resource Guide for Transplant Surveyors.* ONLINE. 2010. Centers for Medicare and Medicaid Services. Available: http://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/downloads/QAPIResourceGuide090810.pdf [29 August 2014].

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal addresses the OPTN key goals of promoting transplant patient safety and improving post-transplant survival. The proposal will provide a tool to the MPSC to encourage and assist OPTN members in the development and implementation of robust QAPI programs. Robust QAPI programs resulting in process and performance improvement will advance these goals of promoting transplant patient safety and improving post-transplant survival.

Plan for Evaluating the Proposal:

The MPSC will monitor the usefulness of this requirement as the Committee continues to evaluate the effectiveness of members' QAPI programs in responding to inquiries and implementing successful improvement processes. This requirement should result in more robust and effective QAPI programs at member institutions which would be evidenced by more proactive responses by members to performance issues and events. Ultimately, the MPSC would expect that more effective QAPI programs will decrease the instances of non-compliance and underperformance. In addition, the Committee will track any unintended consequences that might place an undue burden on members.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and implemented on September 1, 2015.

The MPSC will review compliance with this provision only in conjunction with its review of an identified compliance and performance issue.

Communication and Education Plan:

The proposal addresses new requirements and expectations for members' process improvement. Communication and education efforts will address awareness of the new requirements as well as steps members need to take to fulfill them.

Information about the new requirements would be included in ongoing efforts to inform members about OPTN monitoring for compliance and patient safety, as well process improvement to address areas of concern. The information also would be incorporated into the OPTN Evaluation Plan and included in a crosswalk document that lists CMS and OPTN member requirements in areas of similar authority.

In addition, notification of the amended Bylaws requirements would be included in the following routine communication vehicles:

- Policy notice
- Article on OPTN website and member e-newsletter
- Notification to a listserv group for transplant administrators

Compliance Monitoring:

The MPSC will review compliance with this provision only in conjunction with its review of identified compliance and performance issues. Member compliance will be monitored through requests for submission and MPSC evaluation of a member's performance improvement plans, corrective action plans, plans for quality improvement and information about the members QAPI plan and implementation of that plan.

Policy or Bylaw Proposal:

Appendix B:

Membership Requirements for Organ Procurement Organizations (OPOs)

B.3 Quality Assessment and Performance Improvement (QAPI) Requirement

A. OPOs must develop, implement, and maintain a written Quality Assessment Performance Improvement (QAPI) plan that includes the following elements:

1. QAPI Goals and Statement of Scope

2. Guidelines for Governance and Leadership
   This portion of the plan must include at least all of the following:
   a. How QAPI is integrated into the responsibilities and accountabilities of all members of the OPO, including management and the governing body.
   b. How the OPO will ensure that resources are allocated to implement the QAPI including, who will be accountable for management and coordination.
   c. A plan for leadership, management, and staff training.
   d. A list of the key personnel who will manage QAPI and details on how this group will work together, communicate, and coordinate the reporting of QAPI activities to the governing body.

3. Data Systems and Monitoring
   This portion of the plan must include at least all of the following elements:
   a. Performance indicators that will be monitored on an ongoing basis.

b. Identified data sources and the process for data collection.
c. Description of the process and quality tools used (e.g. pareto charts, scatter diagrams, etc.) for analyzing data.
d. Description of the process for communicating the data and the analysis.
e. Recipients of the data analysis, and the format and frequency.

4. Guidelines for Conducting, Monitoring, and Evaluating Process Improvement Projects
   Describe the overall plan for conducting process improvement projects to improve compliance and performance and the process for evaluating the effectiveness of the process improvements.
5. Adverse Event, Error Identification, and Investigation
   Describe how adverse events and errors will be identified and evaluated. Include guidelines to assess the adverse event and error severity, actions to be taken based on the assessment, and monitoring and evaluation to ensure actions are effective.
6. Communications
   Describe who in the organization will receive QAPI communications, the frequency of those communications and the format in which the information will be provided.
7. Evaluation of QAPI Process
   Describe the process for assessing QAPI in the organization on an ongoing basis.

B. The OPO must document implementation of all of the required elements of the QAPI plan.

B.~~3~~4 Facilities and Services

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

Appendix D:

Membership Requirements for Transplant Hospitals and Transplant Programs

A transplant hospital member is any hospital that performs organ transplants and has current approval as a designated transplant program for at least one organ.

D.1 Transplant Hospital Compliance

No change to this section.

D.2 Designated Transplant Program Requirement

No change to this section.

D.3 Quality Assessment and Performance Improvement (QAPI) Requirement

A. **Transplant hospitals must develop, implement, and maintain a written Quality Assessment Performance Improvement (QAPI) plan. The QAPI plan must incorporate all designated transplant programs at the transplant hospital and must include the following elements:**

1. QAPI Goals and Statement of Scope

2. Guidelines for Governance and Leadership

   This portion of the plan must include at least all of the following:

   a. How QAPI is integrated into the responsibilities and accountabilities of all members of the transplant hospital, including management and the governing body.

   b. How the transplant hospital will ensure that resources are allocated to implement the QAPI including, who will be accountable for management and coordination.

   c. A plan for leadership, management and staff training.

   d. A list of the key personnel who will manage QAPI and details on how this group will work together, communicate, and coordinate the reporting of QAPI activities to the governing body.

3. Data Systems and Monitoring

   This portion of the plan must include at least all of the following elements for each transplant program:

   a. Performance indicators that will be monitored on an ongoing basis.

   b. Identified data sources and the process for data collection.

   c. Description of the process and quality tools used (e.g. pareto charts, scatter diagrams, etc.) for analyzing data.

d. Description of the process for communicating the data and the analysis.

e. Recipients of the data analysis, and the format and frequency.

4. Guidelines for Conducting, Monitoring, and Evaluating Process Improvement Projects

   Describe the overall plan for conducting process improvement projects to improve compliance and performance and the process for evaluating the effectiveness of the process improvements.

5. Adverse Event, Error Identification and Investigation

   Describe how adverse events and errors will be identified and evaluated. Include guidelines to assess the adverse event and error severity, actions to be taken based on the assessment, and monitoring and evaluation to ensure actions are effective.

6. Communications

   Describe who in the organization will receive QAPI communications, the frequency of those communications and the format in which the information will be provided.

7. Evaluation of QAPI Process

   Describe the process for assessing QAPI in the organization on an ongoing basis.

B. The transplant hospital must document implementation of all of the required elements of the QAPI plan.

D.~~3~~4 Facilities and Resources

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

At-a-Glance

Definition of a Transplant Hospital

- **Affected Bylaws:** Bylaws Article 1.2 (Transplant Hospital Members); Bylaws Appendix M (Definitions); Policy 1.2 (Definitions)

- **Membership and Professional Standards Committee (MPSC)**

  The proposed changes to the transplant hospital definition are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when assessing applicant submissions for OPTN membership and transplant program designation. A transplant hospital member is currently defined by OPTN Bylaws as "a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ" and by OPTN Policy as "a health care facility in which transplants of organs are performed". A lack of distinguishing detail in the transplant hospital definition has proven to be problematic when assessing for membership healthcare institutional configurations consisting of multiple "hospitals" performing the same organ transplants at geographically separated sites. Therefore, the goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance concerning patient safety, patient outcomes, and overall compliance with approved OPTN directives.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  This proposal indirectly affects all patients in need of an organ transplant.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The transplant hospital definition reviewed in this proposal is critical for the MPSC to execute its responsibilities of assessing transplant hospitals for transplant safety, performance, and compliance with OPTN Policy and Bylaws. As such, this proposal supports the OPTN's Strategic Plan goals for promoting patient safety and promoting the efficient management of the OPTN. Additionally, the transplant hospital definition is foundational in meeting the requirements found in the Final Rule.

Definition of a Transplant Hospital

Affected Bylaws: Bylaws Article 1.2 (Transplant Hospital Members); Bylaws Appendix M (Definitions); Policy 1.2 (Definitions)

Membership and Professional Standards Committee (MPSC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

The proposed changes to the transplant hospital definition are needed to better describe attributes requiring consideration by the Membership and Professional Standards Committee (MPSC) when assessing applicant submissions for OPTN membership and transplant program designation. A transplant hospital member is currently defined by OPTN Bylaws as "a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ" and by OPTN Policy as "a health care facility in which transplants of organs are performed". A lack of distinguishing detail in the transplant hospital definition has proven to be problematic when assessing for membership healthcare institutional configurations consisting of multiple "hospitals" performing the same organ transplants at geographically separated sites. Therefore, the goal of this proposal is to better define the basic accountable unit in which organ transplantation occurs so that meaningful, accurate, and conclusive assessments can be made regarding transplant program performance concerning patient safety, patient outcomes, and overall compliance with approved OPTN directives.

Background and Significance of the Proposal:

OPTN Policy currently defines a transplant hospital as, "a health care facility in which transplants of organs are performed," and OPTN Bylaws define a transplant hospital member as, "a membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ." These definitions have not been modified since 1986 when they were first adopted by the OPTN Board of Directors. At that time, the OPTN's transplant hospital definitions focused on political and membership representation considerations so that members would have an appropriate say in the development of the national transplant system and organ allocation policies.

These definitions are also important to provide clear parameters of focus for the MPSC in the execution of its responsibilities for making certain patient safety is not in jeopardy, assessing transplant hospitals for outcome performance, and monitoring compliance with OPTN expectations. The evolving structure of medical systems and hospitals has rendered current definitions of a transplant hospital too simplistic, and vulnerable to differing interpretations. For example, consider healthcare systems that include separated and dedicated facilities for pediatric patients. Arguments have been made that approval is only necessary for one transplant hospital in these scenarios, supported by the fact there is a single CMS hospital provider number (CCN) for these healthcare facilities. This perspective disagrees with the MPSC's historical stance on this matter. In deliberating issues related to these types of questions, the MPSC has traditionally abided by the following operational definitions of a transplant hospital:

- A discrete facility where an OPTN approved member transplant hospital performs organ transplants as allowed under its organ transplant program designation and approval
- The basic measurement unit is a single site (hospital)

- A single CCN awarded to distinct and separate hospitals does not mandate OPTN approval as a single member transplant hospital

Historically, there have been a few instances that the MPSC has not held to the above principals due to intervening influences. Subsequent to these actions, the MPSC encountered unwanted consequences which could have been avoided had multiple transplant sites not been allowed to consolidate into a single member and transplant program. An actual example occurred when the MPSC was unable to identify where in a single member's group of transplant facilities possible causes existed which were contributing to transplant performance outcomes falling significantly below the member's expected threshold over multiple continuous cohorts. The same organ was being transplanted at three geographically separated facilities under a single OPTN membership and with a single organ transplant program approval. Ultimately the needed improvements were identified as being required primarily at one facility.

The MPSC often faces the issue of defining a transplant hospital. The last formal position given on the definition of a transplant hospital occurred on November 10, 2010, in a letter to HRSA in which the MPSC Chair stated *"…each transplant hospital facility, at which a same organ type transplant is being performed, must have the required organ transplant program designation approved for that facility. By adopting this principle, the OPTN, at this time, can assure accountability, transparency and monitoring for each transplant program regardless of its ownership and location."*

For the MPSC to uphold its responsibilities of assessing transplant programs in a thorough and accurate manner, it believes hospital specific data is essential regardless of how hospitals have chosen to organize themselves for business or financial purposes. Accordingly, the MPSC recommends expanding the OPTN's definition of a transplant hospital as described in this proposal to eliminate ambiguity and align OPTN Policy and Bylaws with the operational definition of a transplant hospital traditionally used by the MPSC.

The MPSC believes there are numerous strengths with this approach that benefit transplant patients, including:

- Accountability for data, outcome performances, and patient safety resides with a single location
- Since transplant problems/incidents can be pinpointed to a single point of transplant surgery only that location would require a cessation of transplantation instead of all member transplant sites, this allows for all improvement actions taken to be focused on the actual origin of concern
- More closely aligns OPTN definition of "transplant hospital" with CMS definition
- Avoids the need for patients to understand the organization of healthcare facilities relative to where they will actually be transplanted
    - Hospital listing the patient is the same site where the patient will be transplanted
    - Increased transparency with single source data eliminates the burden of sorting through pooled data to determine a single site's performance

The MPSC understands that this approach has the potential to impose some burden on members, specifically the additional cost & administrative efforts necessary for a healthcare system to operate multiple OPTN member transplant hospital operations to accommodate regulatory audits and inquiries. Nevertheless, the Committee believes the positive aspects anticipated to result from the changes outlined in this proposal outweigh the potential negative impacts. Since this

proposal aims to define formally the MPSC's operational definition of a transplant hospital, the potential, additional burden caused by these changes should be limited.

Expected Impact on Living Donors or Living Donation:

This new definition would apply to living donor programs as well as deceased donor programs. However, this proposal is not anticipated to have a direct impact on living donors or living donation.

Expected Impact on Specific Patient Populations:

This proposal has the potential to provide clarity for all transplant candidates listed, or who may be listed, at a multi-hospital healthcare facility; however, it is not anticipated to have a direct impact on any specific patient populations.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal clarifies what are the attributes defining a transplant hospital. This definition is critical for the MPSC to execute its responsibilities of assessing transplant hospitals for transplant safety, performance, and compliance with OPTN Policy and Bylaws. As such, this proposal supports the OPTN's Strategic Plan goals for promoting patient safety and promoting the efficient management of the OPTN.

Additionally, the transplant hospital definition is foundational in meeting the requirements found in the Final Rule. Specifically, §121.10 (b)(3), which states:

§121.10 Reviews, evaluation, and enforcement

(b) *Review and evaluation by the OPTN.* (1) The OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of:

[…]

(iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.

Plan for Evaluating the Proposal:

The impact of this proposal is immediate and evaluation will occur in real time by the MPSC. If the proposed changes are effective, the assessment of new member and transplant program applications will have less uncertainty than they can have now. The applicants will have a clearer description of what a transplant hospital's attributes are so fewer uncertainties should exist to be addressed by the MPSC.

The MPSC fully expects to monitor the impact of these changes and then most likely revisit this subject as healthcare organizational structures continue to change.

Additional Data Collection:

Adoption of this proposal will not result in additional data collection.

Expected Implementation Plan:

The MPSC recognizes that there will still be applicants who may not be covered with the new definition. The MPSC will add to the Evaluation Plan the following language:

A subcommittee of the MPSC will review unclear applicant submissions. The subcommittee will make a recommendation on whether the applicant meets the transplant hospital member definition for the MPSC to consider. The MPSC will submit its recommendation to the Board of Directors for consideration.

The MPSC also recognizes that upon implementation it **must** have an understanding of how currently approved transplant hospitals and its transplant programs comply with the new language. As such, the MPSC plans to review current OPTN transplant hospital members regarding their physical layouts as to exactly where organ transplant surgery is performed by organ. This review will occur within 120 days of the Board approval date. Any approved transplant hospital members identified during this review as not conforming to this definition will be given two years from the date on the OPTN notification letter to take all necessary actions to become compliant.

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and implemented on September 1, 2015. Upon Board approval of the new transplant hospital member definition all new member applicants will be reviewed and approved using the updated definition.

Communication and Education Plan:

If these changes are adopted by the OPTN/UNOS Board of Directors, members will be alerted through a policy notice approximately 30 days after the meeting that the Board discussed this proposal.

Compliance Monitoring:

After reviewing all OPTN transplant hospital members there is no plan to maintain an ongoing compliance monitoring process. If transplant hospital configurations change and the hospital finds itself not in compliance with the existing transplant hospital definition, transplant hospitals are expected to contact the OPTN membership department and discuss its new situation, and if necessary, make all required applications for new membership and transplant program designations.

If the MPSC becomes aware of changes in an approved transplant hospital's configuration, an inquiry will be made to the hospital and assistance will be provided as necessary for the transplant hospital to come into compliance with existing requirements.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Article I: Membership

1.2 Transplant Hospital Members

- ~~A transplant hospital member is any hospital that currently performs organ transplants and has current approval as a designated transplant program for at least one organ.~~ A transplant hospital member is any hospital that has current approval as a designated transplant program for at least one organ.

For the Organ Procurement Transplant Network (OPTN) to successfully meet contractual obligations to monitor member compliance, patient safety and organ allocation, the transplant hospital member must have the following characteristics:

- each organ type is only transplanted in a single, discrete geographic location
- program management occurs under a single hospital administrative structure
- a single, unified medical staff credentialed and governed under the same bylaws exists
- a single, unified nursing staff and administration exists

Organ transplant service lines, conducted separately for the same organ including adult and pediatric, with each service line's transplant surgery being performed in non-contiguous buildings are considered distinct and independent for OPTN monitoring purposes. Applicants in this situation need separate transplant hospital member and transplant program approval for each service line.

Appendix M: Definitions

T

Transplant Hospital Member

~~A membership category in the OPTN for any hospital that has current approval as a designated transplant program for at least one organ.~~

Any hospital that has current approval as a designated transplant program for at least one organ.

Policy 1: Administrative Rules and Definitions

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

T

Transplant hospital

~~A health care facility in which transplants of organs are performed~~.

Any hospital that has current approval as a designated transplant program for at least one organ.

Transplant program
A ~~component~~ specialty service group within a transplant hospital that provides transplantation of a particular type of organ.

At-a-Glance

- **Affected/Proposed Policy:** OPTN Bylaws, Appendix D. 10: *Additional Transplant Program Requirements for Transplant Hospitals and Transplant Programs* and Appendix M. *Definitions*

- **Membership and Professional Standards Committee**

  Currently, transplant program performance monitoring relies almost exclusively on risk-adjusted graft and patient survival rates among recipients. The overemphasis on post-transplant metrics may result in risk-aversion and decreased transplant volumes, and may not be in the best interest of waitlisted patients. Further, post-transplant outcomes may not identify structural problems (e.g., understaffing) that prevent a program from keeping up with the needs of its waitlist population. As such, a more holistic approach to performance monitoring is necessary.

  The purpose of this proposal is to provide the MPSC with a tool, the Composite Pre-transplant Metric (CPM), for identifying kidney and liver programs that may be in need of review based on outlying performance in accepting deceased donor organ offers, transplanting waitlisted patients, and/or mitigating waitlist mortality. The CPM is an aggregate, pre-transplant performance metric that combines programs' acceptance rate, geography-adjusted transplant rate, and waitlist mortality rate observed-to-expected (O/E) ratios into a single number for prioritizing programs for potential review.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors

- **Number of Potential Candidates Affected**
  All patients registered on either the liver or kidney waitlist could be affected due to increased attention on pre-transplant performance metrics. As of August 8, 2014, there were 15,778 registered liver candidates and 101,056 registered kidney candidates.

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal is consistent with the OPTN Final Rule, which stresses the importance of reviewing inter-transplant program variability in waitlist mortality. In addition, the proposal addresses the OPTN key goal of increasing access to transplants.

- **Specific Requests for Comment**
  Should transplant program performance monitoring become more comprehensive by including pre-transplant (i.e. waiting list management) performance in addition to post-transplant outcomes? Is the CPM a reasonable method for creating a more balanced performance assessment and identifying programs that need further inquiry by the MPSC? Readers are encouraged to provide feedback on these particular questions as well as comments on all aspects of the proposal.

Proposal to Implement Pre-Transplant Performance Review by the Membership and Professional Standards Committee

Affected/Proposed Policy: OPTN Bylaws, Appendix D. 10: *Additional Transplant Program Requirements for Transplant Hospitals and Transplant Programs* and Appendix M. *Definitions*

Membership and Professional Standards Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

Currently, transplant program performance monitoring relies almost exclusively on risk-adjusted graft and patient survival rates among recipients. The overemphasis on post-transplant metrics may result in risk-aversion and decreased transplant volumes,[1,2] and may not be in the best interest of waitlisted patients. Further, post-transplant outcomes may not identify structural problems (e.g., understaffing) that prevent a program from keeping up with the needs of its waitlist population. As such, a more holistic approach to performance monitoring is necessary.

The purpose of this proposal is to provide the MPSC with a tool, the Composite Pre-transplant Metric (CPM), for identifying kidney and liver programs that may be in need of review based on outlying performance in accepting deceased donor organ offers, transplanting waitlisted patients, and/or mitigating waitlist mortality. The CPM is an aggregate, pre-transplant performance metric that combines programs' acceptance rate, geography-adjusted transplant rate, and waitlist mortality rate observed-to-expected (O/E) ratios into a single number for prioritizing programs for potential review.

Background and Significance of the Proposal:

Since 1994, the OPTN has reviewed risk-adjusted patient and graft survival outcomes to monitor transplant program performance. The intent of this oversight has been and continues to be to identify opportunities for process improvement that lead to improved patient outcomes. In recent years, members of the MPSC have questioned whether the review of only post-transplant outcomes is broad enough to fully assess whether transplant programs are serving the needs of their patients.

This overly narrow definition of patient outcomes was most evident in several high profile cases of waitlist mismanagement in the early 2000's. In one case, a transplant program did not have a full-time surgeon on-site and was, in turn, unable to keep up with the needs of its waitlisted patients. Deceased donor transplant offers were frequently turned down, transplant volumes decreased, and waitlisted patients were dying at a higher than expected rate. In another example, a newly established transplant program was insufficiently staffed to handle the immediate influx of thousands of patients, substantially affecting patients' access to transplantation. In both of these cases, graft and patient survival rates among recipients were not extraordinary and thus were insufficient for uncovering these systemic cases of waitlist mismanagement. The MPSC's "functional inactivity" thresholds, which trigger a program for review if they have performed zero

[1] Schold JD, Buccini LD, Srinivas TR, et al. The association of center performance evaluations and kidney transplant volume in the United States. Am J Transplant 2013;13:67-75.

[2] Cameron, Andrew M., and Brigitte E. Sullivan. "Regulatory Oversight in Transplantation: There and Back Again." *JAMA surgery* 148.11 (2013): 997-998.

transplants over a specified time frame (e.g., 3 consecutive months for liver, heart, and kidney programs) also did not identify these cases.

In April 2008, the United States General Accountability Office (GAO) issued a report[3] that highlighted these cases and the need to develop and implement "a set of activity-level indicators to detect problems that prolong the time patients wait for transplants." The report emphasized the utility of waitlist activity measures such as transplant rates and organ offer acceptance rates. These "pre-transplant" metrics – risk-adjusted (i.e., "case-mix" adjusted) acceptance rates, transplant rates, as well as waitlist mortality rates – are produced by the SRTR contractor. HRSA charged the OPTN to find ways to use these metrics and perhaps other measures of waitlist activity to expand the suite of performance metrics used to oversee transplant programs.

In 2006, the OPTN's Joint Board-MPSC Process Improvement Working Group began evaluating the usefulness of organ offer acceptance rates and other measures of pre-transplant activity. They observed that while risk-adjusted acceptance rates and transplant rates were correlated (programs with high acceptance rates tended to have high transplant rates), they were not *so* highly correlated as to make either of the two redundant and irrelevant in light of the other. The group concluded that both metrics add value and could be useful for monitoring transplant programs' pre-transplant activity. They also concluded that acceptance rates, though potentially a very powerful metric for identifying programs with waitlist management problems, should be used but *not* as a stand-alone metric.

The Development of a New Metric:

With this mandate to develop an approach for monitoring pre-transplant performance, coupled with the GAO report and the Joint Board-MPSC working group recommendations to use acceptance rates but not as a stand-alone metric, the OPTN contractor developed the Composite Pre-transplant Metric (CPM) for MPSC to consider as a potential approach for identifying programs in need of review. The CPM is a weighted average of the following case-mix adjusted, pre-transplant observed-to-expected (O/E) ratios produced by the SRTR contractor: waitlist mortality rates (liver only), *geography-adjusted* transplant rates, and organ offer acceptance rates. To account for widely varying sample sizes across institutions, the O/E ratios are first attenuated ("shrunken" closer to 1.0) depending on the strength of evidence underlying each program's ratios, using an approximation to the Empirical Bayes[4] method.

The CPM can be interpreted as an "aggregate, pre-transplant O/E ratio," with an average value of around 1.0. Unusually high CPM values - typically associated with high mortality, low transplant, and low acceptance rates - are generally around 1.5 to 2.5, or even higher. Low outlier values, which generally reflect increased waitlist activity and lower mortality rates, tend to be between about 0.50 and 0.75. The CPM is intended to identify programs that *may* have a need for improvement in waitlist management; it is not a definitive indication that a problem actually exists.

Figure 1 shows that the CPM distribution for liver programs is centered around 1.0, with a few programs having values as low as about 0.5, and others having values near or above 2.0. CPM is intended to identify only a small number of programs with highly aberrant pre-transplant performance metrics for further review. In the July 2012 cohort, just 6 (5%) of 130 liver programs had CPM exceeding 1.5, the proposed threshold for triggering MPSC review.

[3] GAO Report on Organ Transplant Programs to the Ranking Member, Committee on Finance, U.S. Senate, April 2008.
[4] Efron, Bradley, and Carl N. Morris. *Stein's paradox in statistics*. WH Freeman, 1977.

The distribution of CPM among liver programs tends to look like this:

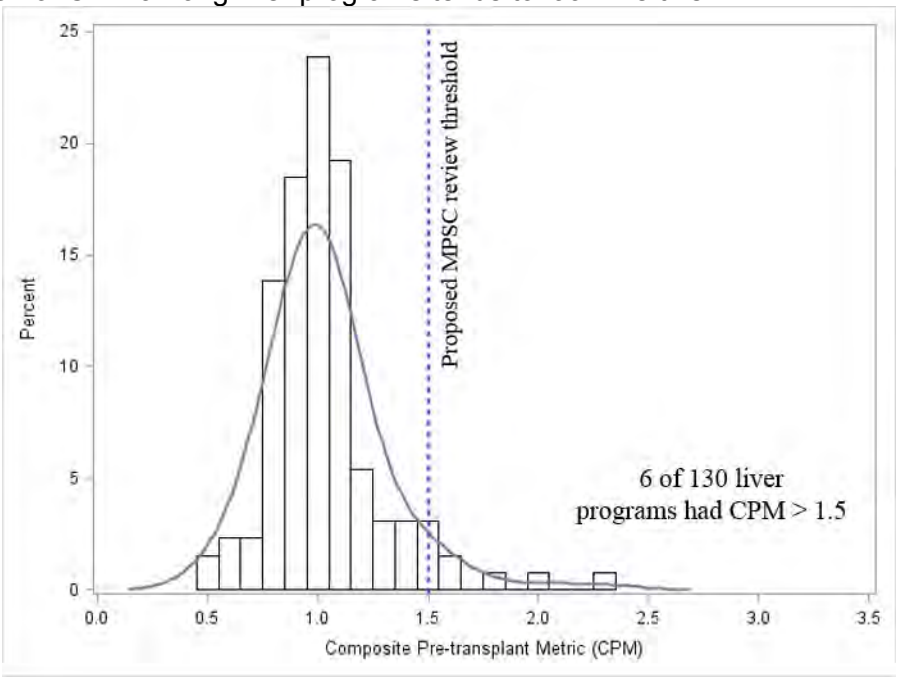


Figure 1. CPM distribution for liver programs, July 2012 PSR cohort (calendar year 2011 data).

The distribution of CPM among kidney programs tends to look like this:

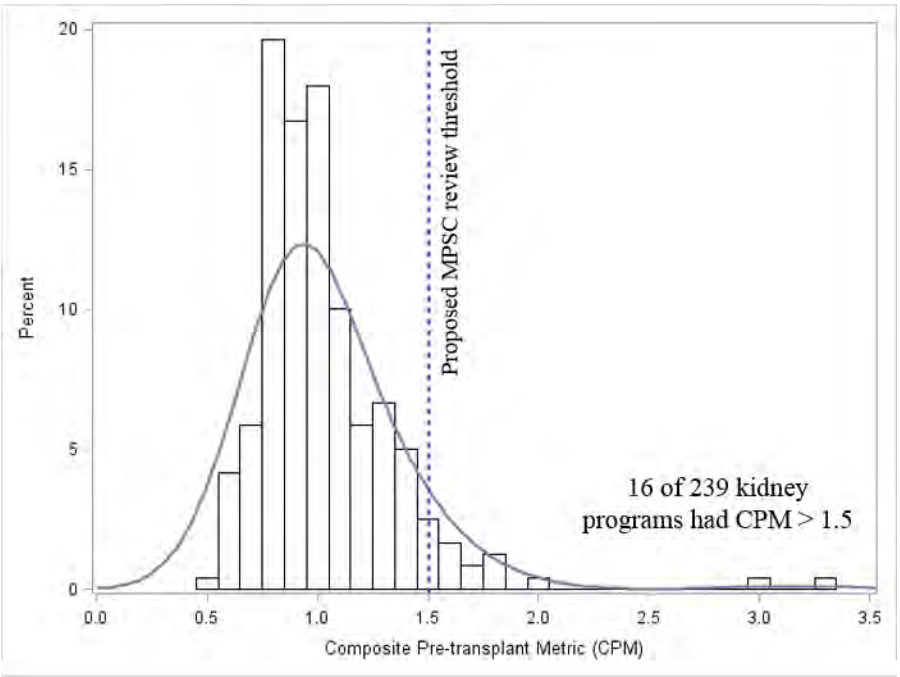


Figure 2. CPM distribution for kidney programs, July 2012 PSR cohort (calendar yr. 2011 data).

Figure 2 reveals a similar CPM distribution for kidney programs compared to liver programs (Figure 1), except for the presence of two programs with extreme values near or above 3.0. In

the July 2012 cohort, just 16 (7%) of 239 kidney programs had CPM exceeding 1.5, the proposed threshold for triggering MPSC review.

Profiles of Programs with Unusually High CPM Values

The liver program with the highest CPM of 2.29 was accepting deceased donor liver offers at a rate only 10% of expected, based on national data and adjusting for donor characteristics (e.g., age, DCD) as well as candidate characteristics (e.g., age, MELD score). In other words, for every ten similar offers accepted by an average program, this program accepted just one. In turn, this program was only transplanting patients at a rate 62% of expected. Also, waitlist mortality was 67% higher than expected, although this rate was not statistically different from expected.

Statistical profiles of liver programs

Pre-transplant metrics for liver program with CPM of 2.29.

- Acceptance rate: O/E = 0.10 (p<0.01) 74 fewer accepted offers than expected.
- Transplant rate O/E = 0.62 (p<0.01) 23 fewer transplants than expected.
- WL mortality rate O/E = 1.67 (p=0.37) 2 more deaths than expected.

Pre-transplant metrics for liver program with the second highest CPM of 2.03:

- Acceptance rate O/E = 0.25 (p<0.01) 44 fewer accepted offers than expected.
- Transplant rate O/E = 0.27 (p<0.01) 41 fewer transplants than expected.
- WL mortality rate O/E = 1.26 (p=0.21) 7 more deaths than expected.

Statistical profiles of kidney programs

Pre-transplant metrics for kidney program with CPM of 3.26.

- Acceptance rate: no offers received
- Transplant rate O/E = 0.06 (p<0.01) 31 fewer transplants than expected. *(Performed two living donor transplants.)*
- WL mortality rate O/E = 1.89 (p=0.03) 7 more deaths than expected.

Pre-transplant metrics for kidney program with the second highest CPM of 2.97:

- Acceptance rates: organ-based O/E = 0.00 (p<0.60), offer-based O/E=0.00 (p<0.15) *(Received just two offers.)*
- Transplant rate O/E = 0.00 (p<0.01) 32 fewer transplants than expected.
- WL mortality rate O/E = 1.55 (p=0.09) 9 more deaths than expected.

Pre-transplant metrics for kidney program with the third highest CPM of 2.04:

- Acceptance rates: organ-based[5] O/E = 0.38 (p<0.01), offer-based O/E=0.31 (p<0.01).
- Transplant rate O/E = 0.54 (p<0.01) 35 fewer transplants than expected.
- WL mortality rate O/E = 1.26 (p=0.17) 6 more deaths than expected.

Several of the programs identified by CPM had already involuntarily inactivated or withdrawn from the OPTN during this period.[6]

[5] CPM is now using an offer-based acceptance rate model, but was originally computed using both organ and offer-based acceptance rate models, as in Wolfe RA, LaPorte FB, Rodgers AM, Roys EC, Fant G, Leichtman AB. Developing organ offer and acceptance measures: when 'good' organs are turned down. Am J Transplant 2007;7:1404-11.

[6] Pre-transplant metrics for programs that closed during the evaluation period may be even more outlying due to abrupt inactivity associated with program closure and a residual waitlist that was not immediately transferred to other program(s).

A New, More Balanced Approach to Performance Monitoring

Monitoring graft and patient survival is vital to ensuring that transplant recipients continue to have good outcomes and that donated organs are used effectively. However, given the substantial net-benefit for most patients of organ transplantation compared to waiting on organ-replacement therapy (if applicable), transplant centers with excellent post-transplant outcomes may not be adequately serving their waitlisted patients if few patients are actually getting transplanted. The use of pre-transplant metrics in conjunction with post-transplant graft and patient survival metrics for performance monitoring (Figure 3) may ultimately be in the best interest of end-stage organ failure candidates on the waitlist.[7]

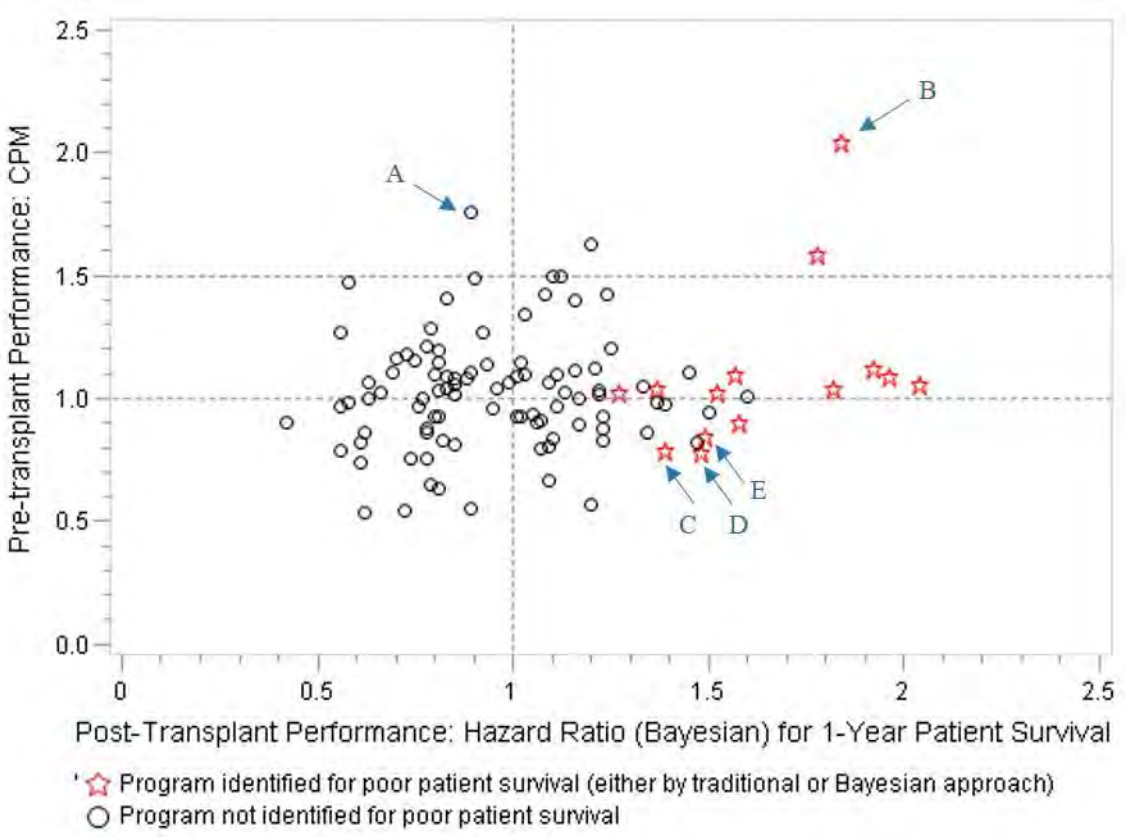


Figure 3. CPM vs. 1-Year Patient Survival Hazard Ratio (Bayesian), for Adult* Liver Programs (n=108). Reference lines indicate the proposed MPSC review threshold of CPM=1.5, as well as the "average" or expected value of 1.0 for both CPM and patient survival hazard ratios. Results based on July 2012 SRTR PSR cohort: pre-transplant metrics derived on calendar year 2011 data; post-transplant O/E derived from recipients transplanted between Jan, 2009 – Jun 30, 2011. *(* Programs having more than 50% pediatric patients on their waitlist during 2011 were excluded from this analysis.)*

While patient survival rates were better than expected (Bayesian HR=0.89) for Program A, this program had a very high CPM of 1.75, suggesting a potential need for review with respect to pre-transplant performance (Figure 3). In fact, this program was accepting liver offers at a rate only

[7] Axelrod, D. A. "Balancing accountable care with risk aversion: Transplantation as a model." *American Journal of Transplantation* 13.1 (2013): 7-8.

58% of expected (p<0.01), was transplanting patients at a rate 63% of expected (p<0.01), and had a mortality rate 2.1 times greater than expected (p<0.01). All considering, this program may have room for improvement in the area of waitlist management/transplant activity in order to more effectively serve the patients on its waitlist. Of course, as further explained in the compliance monitoring section of this document, the CPM merely provides a trigger for further review; in and of itself, this metric does not provide a definitive indication that a systemic issue exists that requires improvement/corrective action.

Transplant program B (Figure 3) may have been in need of process improvements in both pre and post-transplant patient care. To go along with a patient survival hazard ratio of 1.84, this program was only accepting offers at a rate 25% of expected (p<0.01) and transplanting patients at a rate 27% of expected (p<0.01). Program B's waitlist mortality rate was also 1.26, or 26% higher than expected; however, this difference was not statistically significant due to a relatively small number of deaths.

Transplant programs identified for exceptionally poor graft or patient survival rates should, of course, assess whether process improvements are needed, irrespective of how quickly they are transplanting patients on their list. Review of transplant program processes to identify meaningful process improvement areas that improve patient outcomes is, after all, the overriding purpose of MPSC's review of survival rate data. However, some centers identified for review based on moderately poor graft or patient survival rates may, upon closer review, have no obvious need for process improvement. And some of these programs may have excellent pre-transplant metrics, in terms of transplanting patients on their waitlist and mitigating waitlist mortality. The establishment of a pre-transplant metric will provide the MPSC additional information regarding the program's service to its patients to consider when reviewing post-transplant outcomes in addition to its identifying programs that may need improvement in waitlist management.

For example, liver programs C, D, and E (highlighted in Figure 3) have moderately lower than expected patient survival rates (i.e., higher than average Bayesian hazard ratios, between 1.39 and 1.49) and would have been identified for review based on either the traditional identification method, the new Bayesian method, or both methods. However, in aggregate these programs may be serving their waitlist population quite well, given their exceptionally low CPM values. Statistical profiles of these programs reveal that each was accepting liver offers at a rate higher than expected, was transplanting patients at a rate more than 80% above expected, and had waitlist mortality rates lower than (and not statistically different from) expected.

- Liver program C
  - Post-transplant (Bayesian hazard ratios, 1-year survival): patient HR=1.39, graft HR=1.39
  - Pre-transplant: acceptance O/E=1.10 (p=0.41), transplant rate O/E=1.88 (p<0.01), waitlist mortality rate O/E=0.83 (p=0.46)

- Liver program D
  - Post-transplant (Bayesian hazard ratios, 1-year survival): patient HR=1.48, graft HR=1.37
  - Pre-transplant: acceptance O/E=1.33 (p=0.03), transplant rate O/E=1.83 (p<0.01), waitlist mortality rate O/E=0.88 (p=0.62)

- Liver program E
  - Post-transplant (Bayesian hazard ratios, 1-year survival): patient HR=1.49, graft HR=1.38
  - Pre-transplant: acceptance O/E=1.06 (p=0.77), transplant rate O/E=1.92 (p<0.01), waitlist mortality rate O/E=0.97 (p=0.99)

Incorporating the CPM into the Bylaws will allow the MPSC to more formally take into account pre-transplant information when reviewing programs already identified based on post-transplant metrics, to better assess – from a perspective broader than just recipient outcomes – whether each program is effectively serving its patient population. In this way, the CPM has the potential to reduce the emphasis on post-transplant metrics, in particular in cases of borderline-high graft or patient survival hazard ratios, when such programs are reviewed by the MPSC. The CPM will provide the MPSC a tool to evaluate transplant program performance more holistically, including both post-transplant and pre-transplant outcomes.

Calculating the CPM

The SRTR's program-specific waitlist mortality rates, geography-adjusted transplant rates, and offer acceptance rates – adjusted for case-mix and in the form of observed-to-expected (O/E) ratios – are combined into a single composite indicator of pre-transplant performance, the CPM. To account for the statistical uncertainty in O/E's due to varying sample sizes among programs, an approximation to the empirical Bayes estimation method is used to "shrink" each O/E ratio toward the neutral value of 1.0 before combining them. The CPM is a weighted average of these "shrunken" O/E's, with weights determined by the CPM Work Group of the MPSC.

The CPM is calculated in 5 steps.

Step 1. Apply logarithmic transformation of O/E ratios (symmetry)
Step 2. Apply negative sign for transplant and acceptance rates (directional consistency)
Step 3. Account for statistical uncertainty due to finite sample sizes (Empirical Bayes method)
Step 4. Combine into a single metric by applying component weights (composite approach)
Step 5. Apply antilog function (return to familiar O/E scale)

Table 1: CPM Component Weights

Program Type	Mortality Rate	Transplant Rate	Acceptance Rates
Liver	0.50	0.25	0.25
Kidney	0.00	0.50	0.50

An example CPM calculation as well as additional information about the Empirical Bayes method is provided in the appendix.

The CPM "Safety Net"

One benefit of using a composite metric approach for performance evaluation is that the CPM may identify a potential waitlist management issue at a program with *borderline-low* performance in all three metrics, when no *single-metric* threshold would have triggered a review. However, a risk associated with using a composite approach is that extremely poor performance in one particular metric – which may in and of itself be cause for concern – may be offset by good or average performance in the other metric(s). Though it is unlikely that either transplant or acceptance rates could be extremely low while the other was high due to their high correlation, their correlations with waitlist mortality rates are much lower. It is possible for a program to have an extremely high (and statistically higher than average) waitlist mortality rate that is offset by good or average transplant and/or acceptance rates. Though the CPM Work Group agreed that identification of programs based on pre-transplant performance should be primarily driven by the CPM, programs with an extremely high waitlist mortality rate should not be ignored, even if the CPM does not reach the 1.5 threshold. Improvement in patient care or a reevaluation of listing practices may be needed, despite transplant and acceptance rates that conform to national expectations.

Consequently, in addition to program identification using the CPM > 1.5 trigger, the following "safety net" is also part of this proposal.

CPM Safety Net: Waitlist mortality O/E > 2.0 and p-value (one-sided) < 0.05

As shown in Figure 4, only rarely do mortality rates exceed twice the expected value in programs with more than a few patients on their waitlist.

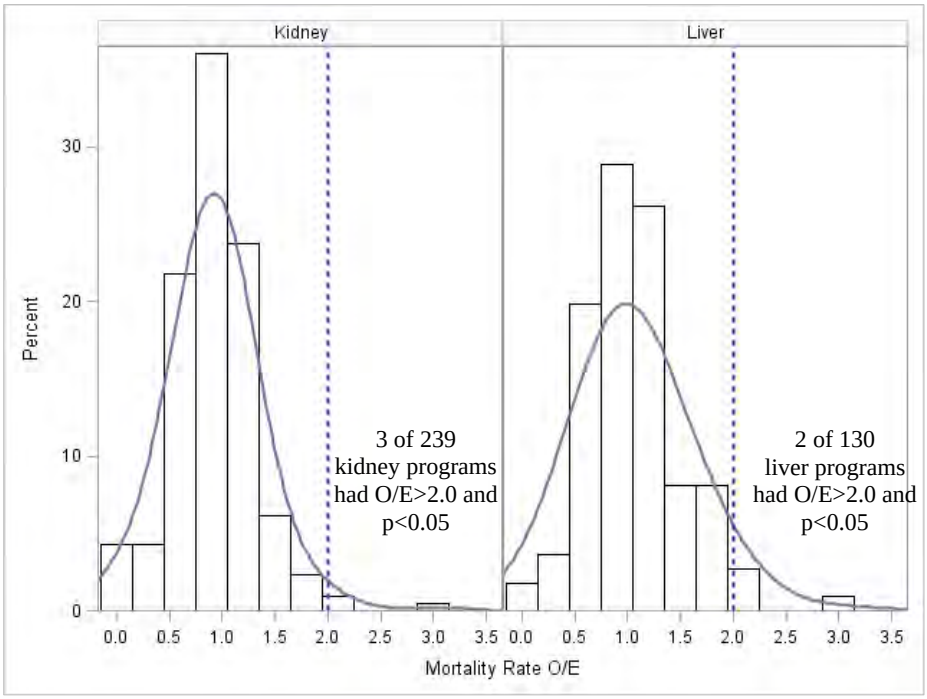


Figure 4. Waitlist Mortality Rate O/E distribution for kidney and liver programs. Programs with less than 20 person-years on the waitlist in 2011 were excluded to avoid including outlier O/E ratios that are driven by small sample sizes and are generally not statistically different from 1.0. Results are based on July 2012 SRTR PSR cohort (calendar year 2011).

The safety net threshold of 2.0 was chosen because it is extreme and represents a 100% increase in waitlist deaths relative to expectations; the intent is to identify very few programs. Even though the waitlist mortality rate was excluded from the CPM for kidney programs due to the reasons explained below, the CPM Work Group concluded that in those rare instances when more than twice the expected number of deaths occurred, such programs should be reviewed.

The Anticipated Number of Programs to be Identified by the CPM and Safety Net

Based on the July 2012 PSR cohort, the following number of programs would have been identified with the CPM methodology:

19 of 239 kidney programs (7.9%):
- 16 with CPM > 1.5
- 3 with mortality O/E>2.0 and p-value (one-sided) <0.05 ("safety net")

8 of 130 liver programs (6.1%):
- 6 with CPM > 1.5
- 2 with mortality O/E>2.0 and p-value (one-sided) <0.05 ("safety net")

Overall, 27 of 369 programs (7.3%) would have been identified for pre-transplant performance review. However, 13 of these programs were already under review by the MPSC for poor post-transplant outcomes or functional inactivity, or had previously inactivated or withdrawn.

Thus, a total of 14 programs (approximately 4% of all kidney and liver programs) would have been *newly identified* for MPSC review by the CPM methodology based on the July 2012 cohort.

Though this number will vary from one review cycle to the next, previous analyses have shown the number of programs exceeding the CPM and mortality rate thresholds has not changed greatly in recent years.

The Underlying Risk-Adjusted Models behind the CPM

Waitlist mortality rates

Waitlist mortality rates measure the number of deaths among waitlisted candidates at a program relative to the number of patient-years after listing during a specific one year cohort period (e.g., July 1, 2012 to June 30, 2013). Patient deaths are identified as waitlist removals for reason of patient death, as well as by supplementary data sources including the Social Security Death Master file and CMS data. Some patient deaths *after* removal from the waitlist, provided they occurred within the specific one-year cohort period, are counted. Deaths after removal for transplant are not counted. Deaths after removal for patient recovery or transfer to another center are also not counted, unless the death occurred within 60 days of removal. Since some deaths *after removal* are counted, this metric is more accurately described as "mortality after listing" as opposed to "waitlist mortality."

There are two mortality rate models, one for kidney and one for liver candidates. These rates are adjusted for candidate factors such as age, gender, blood type, diagnosis, and lab MELD score (liver), which are associated with the likelihood of candidate mortality. By adjusting for these factors, centers with a disproportionate number of patients having a higher likelihood of death; for example, programs with older liver patients with high MELD scores, are not disadvantaged by the

metric. Rather, each program's observed number of patient deaths during the one year period of time is evaluated relative to the expected number of deaths, which is based on the number of person-years and case-mix of patients on their waitlist.

The models, in particular for liver patients, have strong predictive power with respect to waitlist mortality. This predictive ability is measured by the c-statistic, which ranges from 0.50 (no ability to discriminate) to 1.0 (perfect ability). The c-statistics for these models are 0.66 and 0.87 for kidney and liver candidates, respectively.

The following factors are currently included in the waitlist mortality models:

Liver	Kidney
candidate age	candidate age
candidate blood type	candidate blood type
candidate diagnosis	candidate diagnosis
candidate status (laboratory MELD)	candidate gender
candidate gender	candidate race/ethnicity
candidate race/ethnicity	candidate waiting time
candidate waiting time	

Additional documentation for these models can be found on the SRTR's website (http://www.srtr.org/csr/current/Tech_notes.aspx). These models may be periodically updated based on more recent data. These updates may result in changes to the factors included in the models as well as the model coefficients.

Geography-adjusted transplant rates

Transplant rates measure a program's frequency of transplanting patients using either living or deceased donor organs, relative to the number of patient-years on their waitlist. There are two transplant rate models, one for kidney and one for liver candidates. These rates are adjusted for candidate factors such as age, blood type, CPRA (kidney), and MELD score (liver) that are associated with the likelihood of transplantation. By adjusting for these factors, centers with a disproportionate number of patients having a lower likelihood of receiving a transplant; for example, programs with high CPRA blood group B kidney candidates, are not disadvantaged by the metric. Rather, each program's observed number of transplants during the one year period of time is evaluated relative to the expected number of transplants, given the number of person-years and case-mix of patients on their waitlist.

The models have good or excellent predictive power in distinguishing candidates that are likely to be transplanted from those that are not. This predictive ability is measured by the c-statistic, which ranges from 0.50 (no ability to discriminate) to 1.0 (perfect ability). The c-statistics for these models are 0.63 and 0.84 for kidney and liver candidates, respectively.

An important addition to the transplant rate models (based on member feedback) was the *DSA supply-to-demand* component. The supply-to-demand ratio in a DSA is calculated as the number of deceased liver (or kidney) donors recovered during the year divided by the number of waitlisted liver (or kidney) candidates in the DSA at the start of the period. This risk-adjustment factor was added to address concerns about transplant rates not being a fair or reliable way to measure the performance of programs in DSAs with relatively few viable organ donors relative to the number

of candidates. Without this adjustment factor, transplant programs in geographic areas with relatively fewer donors tended to have lower transplant rates and higher CPMs. However, after incorporating the supply-to-demand adjustment factor into the models, this bias was mitigated (Additional information available upon request).

The following factors are currently included in the geography-adjusted transplant rate models:

Liver	Kidney
candidate age	candidate age
candidate blood type	candidate blood type
candidate previous transplant	candidate previous transplant
candidate status (match MELD)	candidate CPRA
candidate waiting time	candidate CPRA x previous transplant (interaction)
DSA supply-to-demand ratio	candidate waiting time
	DSA supply-to-demand ratio

(Because the addition of the supply-to-demand ratio as an adjustment factor was solely for the CPM, the *geography-adjusted* transplant rate models differ slightly from the transplant rate models published on www.SRTR.org. Additional information available upon request) These models may be periodically updated based on more recent data. These updates may result in changes to the factors included in the models as well as the model coefficients.

Offer acceptance rates

The offer acceptance rate models predict the likelihood of a deceased donor kidney (or liver) offer being accepted, based on characteristics of both the donor as well as the candidate to which the offer is being made. There are two acceptance rate models, one for kidneys and one for livers. These models are used to determine the number of expected acceptances for each transplant program, for comparison with their observed number of acceptances during a one year time period. In this way, an acceptance rate O/E ratio is computed for each kidney and liver program.

Only organs that were ultimately accepted and transplanted are included. Candidates that were bypassed by the OPO and thus did not actually receive an offer are also excluded. Offers for candidates that could not have accepted due to already having been transplanted, a positive crossmatch, or requiring a multi-organ transplant where the other organ was not available, are excluded as well. Offers received after (higher allocation sequence number) the candidate that ultimately accepted the offer are also excluded.

An acceptance rate model's ability to distinguish offers that are likely to be accepted from those that are not (i.e., predictive power) is measured by the c-statistic, which ranges from 0.50 (no ability to discriminate) to 1.0 (perfect ability). The c-statistic for the liver acceptance rate model is 0.91. The kidney acceptance rate model, which is being redeveloped, has a c-statistic of 0.70.

The models adjust for factors that affect the likelihood of organ acceptance, based on national offer acceptance and refusal data. For example, donor factors such as age, cause of death, hypertensive history, and serological status can affect the quality, expected longevity, and desirability of the organ and are included in the risk-adjustment models, along with other donor factors. Because these factors are included, a program's expected number of acceptances among kidney offers from hypertensive age 60+ donors, for example, will be lower than if the same

number of offers were received from non-hypertensive kidney donors age 18-39. In this way, programs that receive more “marginal” kidney offers will not be disadvantaged, as their observed number of acceptances will be compared against the national expected number of acceptances for the same types of organ offers.

Similarly, candidate factors associated with likelihood of offer acceptance are included in the models. For example, candidate age, CPRA (kidney), and MELD score (liver) have been shown to relate to the odds of an offer being accepted. Programs with a disproportionate number of candidates having clinical and demographic characteristics associated with increased offer selectivity – for example, unsensitized pediatric kidney patients – will also not be disadvantaged, since their observed number of acceptances will be compared against the national expected number for the same types of organs and candidates.

The following factors are currently included in the offer acceptance rate models:

Liver

donor age
donor blood type
donor DCD
donor history of cancer
donor BUN
donor circumstances of death
donor HTLV
donor administered insulin
donor administered antihypertensives
donor EBV (nuclear antigen)
donor liver biopsy performed
donor liver biopsy (% macro vesicular fat)
donor PHS increased risk
donor protein in urine
donor SGPT/ALT
donor number of transfusions
candidate laboratory MELD score
candidate match MELD and status (1A, 1B)
candidate difference between match & lab MELD
candidate serum sodium
candidate albumin
candidate dialysis in prior week
candidate received HCC exception points
candidate previous malignancy
candidate height
candidate Willing to Accept ABO Incompatible
candidate Willing to Accept HBV Core antibody Positive
candidate Willing to Accept HCV Antibody Positive

Kidney

donor age
donor cause of death
donor gender
donor race/ethnicity
donor height
donor blood type
donor serum creatinine
donor hypertension
donor hepatitis (B or C) status
donor location (local, regional, national)
candidate age
candidate gender
candidate race/ethnicity
candidate height
candidate diagnosis
candidate CPRA
HLA mismatch (A-locus) offer
HLA mismatch (B-locus) offer
HLA mismatch (DR-locus) offer
adult donor / pediatric recipient offer
size of program's waitlist

Liver	Kidney
candidate Willing to Accept Liver Segment	
candidate max distance willing to accept	
candidate minimum age willing to accept	
candidate time on list	
candidate-donor gender match	
candidate-donor ABO compatibility	
offer sequence number	
donor location (local, regional, national)	
estimated travel time	

These models are currently being redeveloped and or refined and may continue to be improved periodically based on more recent data. These updates may result in changes to the factors included in the models as well as the model coefficients.

The Evolution of the CPM Methodology:

The CPM concept was first presented to the MPSC in July of 2009. Due to positive feedback, the CPM Working Group was formed to further explore the utility of this metric. The CPM Work Group first met (by phone) in October 2009 and has had 11 subsequent meetings, including an in-person meeting in Chicago in April 2010.

The CPM concept was presented at the American Transplant Congress in 2011 as well as the Transplant Management Forum in both 2011 and 2012 (Additional information available upon request). In addition, in December 2011 a 52-question survey focusing on pre-transplant processes and requesting feedback on the use of pre-transplant metrics for performance monitoring was sent to 47 kidney and 30 liver programs. In 2012, CPM and other pre-transplant metrics were discussed at the 2012 PSR consensus conference.[8]

Based on feedback from these various venues, CPM work group deliberations, and discussions with HRSA and the current and previous SRTR contractor, the following key decisions were made as the methodology was developed and refined over the past six years.

Rationale for developing a "composite" metric

A composite metric approach was pursued for the following reasons:

1. Incorporate acceptance rates but temper their impact

   A previous joint Board-MPSC work group and the GAO emphasized the importance of using acceptance rates for program monitoring, but the work group recommended they not be used as a stand-alone measure for identifying programs to review.

2. Identify programs in need of process improvement that would not be identified using any single metric alone

[8] Kasiske, B. L., et al. "Report of a consensus conference on transplant program quality and surveillance." *American Journal of Transplantation* 12.8 (2012): 1988-1996.

One benefit of using a composite metric approach for performance evaluation is that the CPM may identify a potential waitlist management issue at a program with borderline-low performance in all three metrics, in cases where no single-metric threshold would have been breached. The use of multiple variables together, as in a multivariable regression model, is a common way to increase predictive power.

3. Provide a convenient summary statistic to help prioritize MPSC resources.

   The CPM approach combines three dimensions of pre-transplant information, plus the statistical uncertainty associated with each, into a single value. In this way, the CPM provides a high-level assessment of "aggregate" pre-transplant performance that can be used to identify programs for review. If it is found that too many (or few) programs are being identified, the threshold can be raised (or lowered) from the initial proposed threshold of 1.5.

4. No single metric perfectly reflects the true state of a program with respect to pre-transplant performance.

   Each pre-transplant metric has strengths and weaknesses in terms of its ability to reliably characterize the pre-transplant performance of a transplant program. All rely on accurate reporting of data and are subject to limitations of our ability to adequately adjust for case-mix and other mitigating factors. And some metrics may be more vulnerable to potential manipulation than others. For these reasons, the CPM Work Group felt more comfortable relying on a composite metric as the primary pre-transplant trigger, as opposed to putting all their "eggs in one basket" for identifying programs to review.

5. Mitigate the effect of geography (local organ supply relative to demand)

   Since transplant rates are highly influenced by geography, use of a composite metric would help mitigate the impact of local supply-to-demand dynamics outside the control of transplant programs, since it includes other measures less influenced by geography. This particular rationale for using a composite metric approach became less relevant after the CPM Work Group recommended that the risk-adjusted transplant rates used in the CPM be explicitly adjusted for the supply-to-demand ratio of each DSA.

Rationale for the chosen CPM component weights

The initial weights proposed for the CPM were the same for both kidney and liver programs: 50% for waitlist mortality rates, 25% for transplant rates, and 25% for acceptance rates. An analysis performed for the committee showed that this choice of weights differed very little – in terms of the programs identified as having outlying CPM values – from use of a simple average (33%, 33%, 33%).

At its in-person meeting in April, 2010, the CPM Work Group discussed the inclusion of waitlist mortality rates as a component of the CPM. It was concluded that this factor should be removed from the CPM for kidney programs, for the following two reasons:

- There are insufficient data to adjust for cardiovascular risk factor(s) of kidney candidates

- Waitlist mortality is less under the control of transplant programs, since waitlisted patients are often cared for by nephrologists or primary care physicians

The CPM component weights for kidney programs were subsequently modified to 0%, 50%, 50% for waitlist mortality, transplant, and acceptance rates, respectively.

Only a very small number of transplant programs are known to have had severe, structural problems (e.g., gross staffing shortage) in managing their waitlist to such an extent that caused patients to be at risk. One reason for this may be simply that such egregious cases are very rare; however, another contributing factor may be that programs have not yet been routinely reviewed based on pre-transplant performance, which highlights the impetus for this proposal. With such a small sample size, in terms of the number of historically known problem programs, use of mathematical optimization (e.g., regression analysis) to determine the appropriate weights was not possible. Consequently, the weights were judgmentally derived and agreed upon by the CPM Work Group and MPSC. The use of expert opinion in developing composite metrics is not without precedent.[9]

These weights were *not* chosen by analyzing data for the two high profile cases of waitlist mismanagement in the mid-2000's. The CPM Work Group gained confidence in this new metric when it was demonstrated that both programs would have stood out as outliers with respect to CPM during their crisis periods, had the metric been available at the time. This "validation" of the CPM is described further in the *Additional Evidence Supporting this Proposal* section of this document.

Finally, though the waitlist mortality rate is given the highest weight (50%), it is important to recognize that transplant and acceptance rates both actually have a much larger influence on the liver program CPM. Counterintuitively, despite the smaller component weights of 25%, these factors contribute more to the program-to-program variability in CPM. This is because there is far more program-to-program variability in risk-adjusted transplant and acceptance rates compared to risk-adjusted mortality rates, where differences tend to be smaller and/or statistically insignificant.

Decision to adjust the transplant rate for geography inequities (supply-to-demand)

Transplant rates can be highly influenced by a transplant program's geographic location. Due to substantial differences in the available supply of donor organs relative to demand (size of the local waitlist) across DSA's, transplant rates vary significantly by geography. Some transplant programs responded to a CPM/pre-transplant process metrics survey with concerns that the use of transplant rates wouldn't be fair in light of geographic differences in access to organs, in particular for geographically isolated programs in areas of high waitlist demand (Additional information available upon request).

[9] Saisana, Michaela, and Stefano Tarantola. *State-of-the-art report on current methodologies and practices for composite indicator development*. European Commission, Joint Research Centre, Institute for the Protection and the Security of the Citizen, Technological and Economic Risk Management Unit, 2002.

In response, the CPM Work Group agreed that a supply-to-demand adjustment be added to the transplant rate model, mitigating the bias of transplant rates with respect to the local supply-to-demand ratio (Additional information available upon request). The Work Group believes that this important revision to the transplant rate model is a significant step in responding to member feedback and creating a fairer metric that is better suited for evaluating transplant program performance.

The Work Group also discussed whether "supply" should include all deceased (kidney or liver) donors recovered in the DSA or if ECD, DCD, and/or high KDPI donors should be excluded. After data review and deliberation, the group determined that *all* recovered (kidney or liver) donors should be used to define DSA supply-to-demand ratios (Additional information available upon request).

The "demand" is defined as the total number of waitlisted patients on the liver (or kidney) waitlist in the DSA. Both active and inactive patients are included.

Decision to include both deceased and living donor transplants in transplant rate model

The SRTR contractor has been producing two types of risk-adjusted transplant rates: one that includes only deceased donor transplants, and the other that includes both deceased and living donor transplants. For kidney transplant programs, as well as a few liver programs, the difference in results (O/E) can be significant depending on which approach is used.

The CPM Work Group debated this issue extensively and reviewed data analyses (Additional information available upon request). They reached a consensus and agreed that transplant rates used in the CPM should include both living and deceased donor transplants, for the following reasons:

1. Philosophically, programs should be evaluated on whether they are effectively serving their waitlisted patients using whatever sources of transplantable organs are available, whether from living or deceased donors.

2. Kidney programs that perform a high percentage of living donor transplants tend to be more selective in accepting deceased donor offers. Excluding living donor transplants would have a disproportionate and unfair effect on such programs.

3. It is impossible from currently available data to distinguish these four categories of waitlisted patients:

    a. Waiting strictly for a deceased donor offer
    b. Waiting primarily for a deceased donor offer; may pursue living donation
    c. Primary intent is living donation (e.g., KPD); considering deceased donor offers
    d. Sole intent is to receive a living donor transplant

While living donor transplants can be excluded from the numerator of the transplant rate calculation, without the ability to identify these groups, candidates waiting solely or

primarily for a living donor transplant cannot be excluded from the denominator (patient-years). Consequently, it is not currently possible to develop a pure, "deceased donor activity only" transplant rate model.

One weakness of using the "all donors" version of the transplant rate is that it might unfairly and artificially inflate transplant rates for programs who add to the waitlist candidates that are solely intent on pursuing a living donor transplant, with no intention of accepting a deceased donor organ offer. And, as of September 1, 2014, all candidates for transplantation – even those that are only interested in a living donor transplant – are now required to be added to the waitlist. However, programs are now able to indicate in UNet^{sm} that patients are being added strictly for living donation, offering the possibility of a more refined transplant rate calculation in the future.

Decision to include inactive patient-years in the transplant and mortality rate denominators

Both active and inactive patients are included in the denominators ("patient-years") of the transplant and mortality rate models. These are included because of philosophical ("intent-to-treat") as well as practical considerations ("avoiding gameability"). When a candidate is added to the waitlist, the transplant program is considered to have formally communicated both to the patient and the OPTN an intent-to-treat through the modality of transplantation. The Work Group agreed that transplants and deaths should be evaluated relative to all waitlisted patients, even those who are temporarily in inactive status.

Only including active patients renders the possibility of manipulating the transplant rate metric by setting groups of patients to inactive status during a time a program is having difficulty managing its waitlist. Furthermore, another component of the CPM – the acceptance rate – already has the potential to be affected by setting patients to inactive status, since such patients will not receive offers. The Work Group did not want all of the metrics to be able to be influenced by setting patients to inactive status.

Analyses have shown little or no relationship between programs' CPM and the percent of their list that is in inactive status (Additional information available upon request). Programs were found to have low, moderate, and high CPM all along the inactivity spectrum from those having very few inactive patients to programs with upwards of 80% of their list inactive.

Choice of CPM > 1.5 threshold for identifying programs

The CPM was developed such that higher values were associated with higher waitlist mortality rates, lower transplant rates, and/or lower acceptance rates (Step 2 in *Calculating the CPM*, above). This choice of scaling ("lower is better") was arbitrary but was selected to parallel post-transplant outcomes (graft failure and patient death O/E's).

The CPM threshold of 1.5 was also initially considered because it mirrors the O/E > 1.5 threshold traditionally used in evaluating post-transplant outcomes. As shown in Figures 1 & 2, the value of 1.5 occurs in the tail of the distribution, identifying only a relatively small number of programs that appear to be outliers in terms of pre-transplant performance. The CPM Work Group reviewed statistical profiles of programs with CPM > 1.5 and agreed that based on this underlying data, such programs should be reviewed for pre-transplant

performance. Finally, both of the high profile programs with severe waitlist mismanagement issues would have had a CPM exceeding 1.5 during their crisis periods.

CPM and pediatric patients

The CPM Work Group had extensive deliberations about the implications of CPM on pediatric patients. Currently, pre-transplant metrics are not produced separately for pediatric and adult patients. Rather, these metrics (and, in turn, CPM) include performance on both pediatric and adult patients together. Though most programs tend to predominantly serve either pediatric patients or adult patients, some programs serve a significant mix of both types of patients.

Table 2: CPM for Pediatric vs. Adult Programs
Based on January 2010 PSR Cohort

Organ	Predominant Program Type*	Number of Programs	CPM Stats		CPM Percentiles				
			Mean	Stdev	P5	P25	P50	P75	P95
Kidney	**Adults**	209	0.99	0.21	0.74	0.85	0.94	1.08	1.34
Kidney	**Peds**	34	0.99	0.17	0.76	0.90	0.97	1.04	1.36
Liver	**Adults**	104	1.04	0.28	0.68	0.83	0.96	1.24	1.59
Liver	**Peds**	22	1.03	0.25	0.80	0.91	0.99	1.06	1.46

** Programs with more than 50% of pediatric patients considered predominantly pediatric programs.*

In an analysis shown to the CPM Working Group in April 2010 (Table 2), the CPM distribution was shown to be very similar for predominantly adult vs. pediatric programs, suggesting CPM is not biased with respect to pediatric programs.

Creating separate pre-transplant metric O/E's, and CPM values, for pediatric patients separately from adult patients has been discussed and could be considered for a future revision to the CPM methodology.

Decision to switch to an offer-based model using all organs

The CPM was initially developed using both an offer-based and an organ-based model. In the offer-based model, an organ refused for multiple candidates on a program's waitlist would be counted as multiple refusals, whereas the organ-based model would just consider it as one refused organ. Furthermore, these models only included "good" organs, excluding ECD's, DCD's, and other "marginal" or *difficult to place* organs from the calculations.[10]

The current SRTR contractor has recently made improvements to the liver acceptance rate model, including moving to a single, offer-based model that includes all organs that were ultimately accepted and transplanted. Based on a sensitivity analysis that showed very little changes in the CPM when switching to the new modeling approach, the CPM Work Group agreed to adopt the new approach as part of the CPM (Additional information available upon request).

[10] Wolfe RA, LaPorte FB, Rodgers AM, Roys EC, Fant G, Leichtman AB. Developing organ offer and acceptance measures: when 'good' organs are turned down. Am J Transplant 2007;7:1404-11.

This model is described in more detail in the *The Underlying Risk-Adjusted Models behind the CPM* section of this document.

Decision to remove transplant rates from the "safety net" component of the CPM approach

A final change adopted in 2014 by the CPM Work Group and MPSC was to remove the transplant rate component of the CPM safety net. Previously, the safety net element of the CPM approach would identify programs with mortality rate O/E > 2.0 (one-sided $p<0.05$) *or* transplant rate O/E < 0.25 (one-sided $p<0.05$). Due to concerns about using the transplant rate as a stand-alone metric, the Work Group decided to remove this element of the safety net but leave the mortality rate component.

Further evolution of the CPM may be needed after the committee has had a chance to review some programs based on pre-transplant performance. These reviews may reveal false positives, and false negatives may also be discovered. Modifications to the CPM methodology, the review threshold, and/or component models may be needed in the future.

Alternative Approaches Considered:

During the course of developing and refining the CPM methodology, engaging the transplant community, and in committee deliberations, the following alternative approaches for pre-transplant performance monitoring were considered but ultimately not endorsed by the committee.

1. Using acceptance rates alone

2. Using transplant rates alone

3. Using a transplant rate threshold, a mortality rate threshold, and an acceptance rate threshold independently

4. Using a metric such as Life Years from Listing (LYFL) that combines both pre and post-transplant performance

5. Using a metric that measures how well hospitals are serving patients with end-stage organ disease in their geographic area, not just those that have been waitlisted

6. Using a statistical process control (SPC) technique such as CUSUM in lieu of developing a cohort-based pre-transplant metric for identifying programs

Further explanation of these alternatives and the rationale for proposing the CPM approach can be found in the appendix.

Intended Effects of this Proposal:

It is intended that this proposal will identify a small number of transplant programs with extreme, outlying pre-transplant performance indicators. The MPSC will inquire about such programs in an attempt to determine if process improvements are necessary. If so, it is expected that these programs' pre-transplant performance will eventually "normalize" to some degree, reducing the overall variability among programs in pre-transplant metrics.

The MPSC may also become aware of programs with potentially exemplary pre-transplant performance based on these new metrics. Understanding the practices of these programs may provide insight into ways other programs may be able to improve in terms of effectively serving their waitlists.

It is also expected that some transplant centers may become less risk averse due to the increased emphasis on pre-transplant metrics. This may lead to an increase in the number of liver and/or kidney transplants performed nationally, as well as a decrease in liver and/or kidney discard rates. This may also lead to increases in the number and characteristics of donors recovered for the purpose of transplantation.

Potential Unintended Consequences:

Increased aversion to adding higher-risk patients to the waitlist

It is possible that some centers may decide to add fewer patients to the waitlist, in particular patients considered to be harder to transplant and/or with higher likelihood of waitlist mortality, in response this proposal. Research suggests that this behavior change – listing fewer high-risk patients – has already been taking place due to concerns with post-transplant monitoring[11]. It is unknown whether this aversion to listing patients will increase beyond the current level.

It is important for transplant programs to be fully aware of the effectiveness of the statistical adjustment for various risk factors before deciding to be more selective in listing patients. For example, both the liver transplant rate model and waitlist mortality model adjust for each patient's MELD score at listing, since patients with higher MELD scores are likely to be transplanted more quickly, but also have a higher likelihood of death after listing. Some programs have expressed concern about listing low-MELD patients in light of pre-transplant performance evaluation; however, analyses have shown little to no discernible relationship between liver programs' CPM and the percent of their waitlist with MELD of 18 or higher. Programs were found to have low, moderate, and high CPM regardless of whether they had just 10% or upwards of 50% of their patients with MELD of 18+. (Additional information available upon request).

These pre-transplant statistical models have c-statistics ranging from 0.63 to 0.91, suggesting good or excellent ability to predict likelihood of organ acceptance, transplantation, and mortality after listing. *Programs performing better than national averages with respect to certain patient subpopulations may actually worsen their pre-transplant O/E's by changing listing practices.* On the other hand, for some programs, tightening patient selection criteria may be warranted, not to manipulate the metrics, but because process improvements are needed in the area of pre-transplant patient care and reducing waitlist mortality.

Use of CPM by payers

The CPM was developed to be used within the confines of the OPTN for the purpose of identifying process improvement opportunities. It was not developed for use in determining transplant hospital reimbursement or for public consumption, and the OPTN does not intend to have CPM published on any publicly available website.

[11] Schold JD, Arrington CJ, Levine G. Significant alterations in reported clinical practice associated with increased oversight of organ transplant center performance. Prog Transplant 2010;20:279-87.

The CPM (and CPM-specific subcomponent model results) will be provided to the MPSC's PAIS for review of transplant programs. Transplant programs will also be able to access their own pre-transplant results.

Additional Supporting Evidence:

In addition to the previously referenced analyses, the following information is presented in support of this proposal.

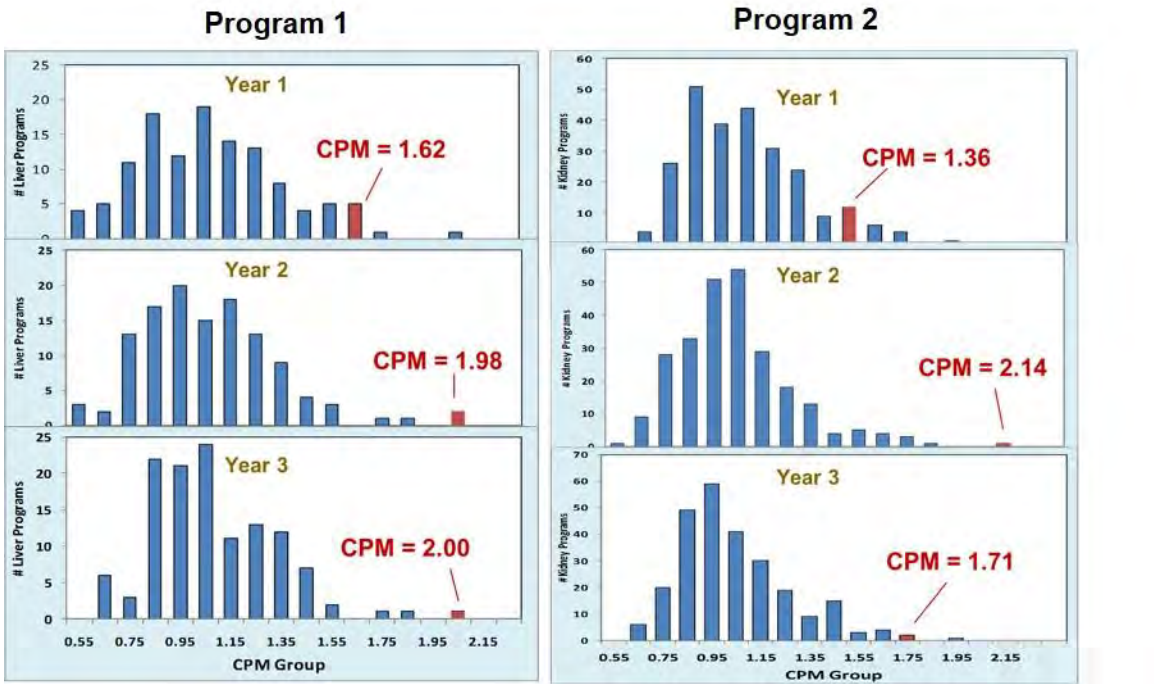


Figure 5. Retrospectively calculated CPM for two programs grossly unable to manage their waitlist. These programs had outlying CPM values during their crisis periods.

Though motivated (in part) by the two programs found to have severe waitlist mismanagement in the mid-2000's, the CPM was not designed by analyzing data from these two high profile cases. However, as shown in Figure 5, both programs would have stood out as outliers with respect to CPM during their crisis periods, had the metric been available at the time. Though this analysis does not represent a complete "validation" of the CPM, it provided the working group and MPSC with increased confidence that the metric would, at minimum, achieve the goal of identifying egregious waitlist management issues.

In addition to analyses supporting the analytical decisions made in developing the CPM, clinical research suggests that centers' *median waiting time to transplant* is a more important center-level factor than recipient outcomes for predicting survival of waitlisted patients.[12] This research highlights the importance of including both pre-transplant waitlist management and post-transplant patient and graft survival in reviews of overall program performance.

[12] Schold, Jesse D., et al. "The pivotal impact of center characteristics on survival of candidates listed for deceased donor kidney transplantation." *Medical care* 47.2 (2009): 146-153.

Expected Impact on Living Donors or Living Donation:

Since the transplant rate being used in the CPM counts both deceased and living donor transplants, it is conceivable that some programs may consider ways to develop or expand their living donor transplant services to further meet the needs of their waitlisted patients.

Expected Impact on Specific Patient Populations:

The Bylaw revision has no known impact for specific patient populations.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal is consistent with the OPTN Final Rule, which stresses the importance of reviewing inter-transplant program variability in waitlist mortality. In addition, the proposal addresses the OPTN key goal of increasing access to transplants. Specifically, the proposal helps the OPTN meet the objective of promoting the best use of donated organs. The proposal provides a meaningful metric to identify potential issues with pre-transplant performance and waiting list practices, in addition to identifying best practices. The strategic plan includes many areas for focus including sharing best practices with the transplant community as well as facilitating patient access. This metric will be used to evaluate member programs that may not be effectively managing the waiting list and identify opportunities to increase access to transplantation.

Plan for Evaluating the Proposal:

The MPSC will monitor whether the new methodology is identifying those transplant programs that are truly underperforming in meeting the needs of their waitlisted patients. The distribution of CPM will also be closely tracked to see if changes to the methodology and/or review threshold are needed.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If successful, this proposal will be considered by the Board of Directors in June 2015. If approved by the Board, implementation of this proposal will be guided by the SRTR's schedule for producing pre-transplant program performance metrics, as well as the development of a process for routine calculation of the CPM and dissemination of this information to the MPSC and members. It is expected that the review of pre-transplant performance will initially be implemented for liver and kidney programs only since all of the models used by the CPM analysis have not yet been developed for other organs.

This proposal will not require programming in UNet℠. The CPM (and CPM-specific subcomponent model results) will be provided to the MPSC's PAIS subcommittee for blinded review of transplant programs, but the OPTN does not intend to publish the CPM on any publicly available website. Transplant programs will be able to access their own CPM and pre-transplant results.

Communication and Education Plan:

The proposal addresses new methodology for assessing member performance and process improvement. Communication and education efforts will address awareness of the new system, the factors that are used to assess pre-transplant outcomes, and how the metrics will be used in member monitoring.

Information about the new model would be included in ongoing efforts to inform members about monitoring of member performance, including educational presentations such as webinars or e-learning modules. The OPTN Evaluation Plan would also be updated with information about the metrics and their applicability to monitoring of member performance.

In addition, notification of the amended bylaw requirements would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Article on OPTN website and member e-newsletter
- Notification to a listserv group for transplant administrators

Compliance Monitoring:

This proposal introduces a new tool for performance monitoring of transplant programs. Currently, the MPSC's review of performance monitoring is limited to post-transplant patient and graft survival and functional inactivity defined by the lack of transplant activity for a specified period. The addition of monitoring of pre-transplant waiting list management will provide the MPSC with a more balanced view of a program's overall performance. The MPSC anticipates that the review of pre-transplant metrics by the Performance Analysis and Improvement Subcommittee (PAIS) will be similar to our current process for review of post-transplant survival and functional inactivity. The MPSC will evaluate the effectiveness of this process and consider revisions to the process as well as the CPM methodology and review threshold, if deemed appropriate.

Falling below either the CPM or mortality rate safety net threshold contained in the proposal will trigger an inquiry by the PAIS. The inquiry will request information relevant to the transplant program's waiting list management process and any unique clinical aspects (i.e., potential mitigating factors) that may influence its ability to meet the thresholds. In its review, the PAIS will consider other available metrics as well as information submitted by the member to determine if the program is truly underperforming and in need of assistance to improve. The PAIS will have the same options as those available for post-transplant and functional inactivity reviews, including:

> **Release from reporting**: the PAIS may recommend releasing a program from review if satisfied that the issues that led to review have been addressed by the program and/or the program's pre-transplant performance has improved. Releasing a program from reporting does not mean that the program is no longer subject to performance reviews conducted by the PAIS. Rather, the program is released from actively reporting to the PAIS at that time. A program can be introduced back into the PAIS performance reviews if, in subsequent cohorts, it does not meet the performance thresholds established by the PAIS.

Continue to report: In its simplest form, a recommendation for continued monitoring by the PAIS is a recommendation for continued reporting for the next meeting cycle. The subcommittee will request the submission of additional information to further assess factors contributing to a program's lower than expected performance and the program's improvement efforts.

Informal Discussion: Programs may be offered the opportunity to meet with the PAIS informally, through a teleconference. An informal discussion provides the members of the PAIS the ability to ask questions of program personnel in real time, and allows the program personnel to address issues that are sometimes hard to summarize in the paper submissions. Programs can be invited to participate in an informal discussion with the PAIS if the program has not been able to identify steps to improve patient outcomes, there has been an apparent lack of progress in implementing the site visit recommendations, or if the PAIS simply wishes to discuss particular issues with the program. An informal discussion does not constitute an adverse action.

Peer Visit: Some programs may be recommended to undergo a peer review site visit. Typically, programs must be under review for at least two MPSC cycles before the PAIS makes this recommendation, and the program has not been able to identify steps to improve patient outcomes and/or there has been an apparent lack of progress in implementing improvements. The peer visit team would generally include a transplant surgeon, physician, and administrator, and is supported by a UNOS staff member. Typically, the panel would be on-site for two days to conduct interviews of all key personnel to the program, including ancillary support, as well as an in-depth review of the relevant patient charts. At the conclusion of the site visit, the panel would provide the center with a preliminary (verbal) summary of its findings. A formal report would be submitted to the PAIS for issuance to the program.

Once a program has undergone a peer visit and received the report, the PAIS would request a plan for quality improvement be submitted in response to the recommendations contained within the report. The Committee would continue to monitor the program's progress in implementing the site visit recommendations.

Voluntary Inactivation: In those rare instances where the review of a program raises concerns for patient safety, the MPSC may recommend that a member inactivate a program or a component of a program, or withdraw its designated transplant program status. Programs that do not voluntarily inactivate or withdraw membership status may be recommended for other action, such as probation or member not in good standing under Bylaws, Appendix L. 15. OPTN Determinations and Actions.

Bylaw Proposal:

D.10 ~~Additional Transplant Program Requirements~~ Transplant Program Performance Reviews

The MPSC will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures.

Transplant program performance reviews will be used to determine if the lower than expected performance can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program, the member, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will constitute a violation of OPTN obligations.

As part of this process, the MPSC may conduct a peer visit to the program at member expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L* of these Bylaws. The informal discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.

The MPSC may recommend that a member inactivate a program or a component of a program or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws.

A. Pre-Transplant Performance Reviews

MPSC review of transplant program performance can be triggered through a review of pre-transplant metrics including waiting list mortality rate, transplant rate, and offer acceptance rates.

The MPSC will review a transplant program based on pre-transplant performance if the program meets *either* of the following criteria over a 1-year period:

- The composite pre-transplant metric (CPM) is greater than 1.5
- The waiting list mortality rate observed to expected ratio is greater

than 2.0 and the one-sided p-value is less than 0.05

B. Post-Transplant Performance Reviews

MPSC review of transplant program performance can be triggered through a review of the one-year graft and patient survival rates. The MPSC will review a transplant program if it has a low survival rate compared to the expected survival rate for that transplant program. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.

For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:

1. The probability is greater than 75% that the hazard ratio is greater than 1.2.

2. The probability is greater than 10% that the hazard ratio is greater than 2.5.

For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.

D.~~10~~ 11 Additional Transplant Program Requirements

~~A. Transplant Program Survival Rates~~

~~The MPSC will conduct reviews of transplant program performance to identify underperforming transplant programs and require the implementation of quality assessment and performance improvement measures. One measure of transplant program performance is triggered through a review of the one-year graft and patient survival rates. The MPSC utilizes performance metrics produced by the Scientific Registry of Transplant Recipients (SRTR) as the principal tool to identify transplant programs that have lower than expected outcomes.~~

~~For programs performing 10 or more transplants in a 2.5 year period, the MPSC will review a transplant program if it has a higher hazard ratio of mortality or graft failure than would be expected for that transplant program. The criteria used to identify programs with a hazard ratio that is higher than expected will include *either* of the following:~~

~~1. The probability is greater than 75% that the hazard ratio is greater than 1.2.~~

~~2. The probability is greater than 10% that the hazard ratio is greater than 2.5.~~

~~For programs performing 9 or fewer transplants in a 2.5 year period, the MPSC will review a transplant program if the program has one or more events in a 2.5 year cohort.~~

~~The MPSC review will be to determine if the higher hazard ratio or events can be explained by patient mix or some other unique clinical aspect of the transplant program. If a program's performance cannot be explained by patient mix or some other unique clinical aspect of the transplant program, the program, in cooperation with the MPSC, will adopt and promptly implement a plan for quality improvement. The member's failure to adopt and promptly implement a plan for quality improvement will constitute a violation of OPTN obligations.~~

~~As part of this process, the MPSC may conduct a peer visit to the program at member expense. The MPSC may also require, at its discretion, that the member participate in an informal discussion. The informal discussion may be with the MPSC, a subcommittee, or a work group, as determined by the MPSC. The informal discussion will be conducted according to the principles of confidential medical peer review, as described in *Appendix L* of these Bylaws. The informal discussion is not an adverse action or an element of due process. A member who participates in an informal discussion with the MPSC is entitled to receive a summary of the discussion.~~

~~The MPSC may recommend that a member inactivate a program or a component of a program or withdraw its designated transplant program status based on patient safety concerns arising from review of the program's graft and patient survival. If the program fails to inactivate or withdraw its designated transplant program status when the MPSC recommends it do so, the MPSC may recommend that the Board of Directors take appropriate action as defined in *Appendix L: Reviews, Actions, and Due Process* of these Bylaws~~.

~~B~~A. Patient Notification Requirements for Waiting List Inactivation

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

Appendix M. Definitions

Composite Pre-Transplant Metric (CPM)
The composite pre-transplant metric (CPM) is an aggregate, pre-transplant observed to expected ratio that combines observed to expected ratios of waiting list mortality rate, transplant rate including deceased and living donor recipients, and offer acceptance rates into one number. The CPM for kidney programs does not include an observed to expected ratio for waiting list mortality rate.

Appendix A

Alternative Approaches Considered

1. Using acceptance rates alone

Instead of using a composite metric approach, a simpler alternative would be to use offer acceptance rates alone to identifying programs for MPSC review. Of the three metrics – transplant, mortality, and acceptance rates – it is the acceptance rate over which transplant programs may have the most direct influence. However, the following reasons support use of the composite approach as opposed to relying on acceptance rates alone for performance monitoring.

- A prior Joint Board-MPSC Work Group reviewed acceptance rate data, and though they found the acceptance rate to represent a potentially useful and powerful metric for identifying anomalous transplant program performance, the group recommended that acceptance rates *not* be used as a stand-alone metric for identifying programs.
- Though acceptance rates are correlated with transplant rates, not explicitly including transplant rates in pre-transplant performance monitoring could result in future programs with systemic waitlist management issues not being identified for corrective action. Two high profile cases in the mid-2000's of transplant programs being grossly unable to meet the needs of their waitlisted patients was one of the key motivating factors for the CPM. An analysis showed that while acceptance rates were generally lower than expected for these two programs, it was their transplant rates that most stood out as being aberrant compared to the rest of the country (Additional information available upon request).
- During the lengthy process of vetting and refining the CPM over the course of five years, the CPM Work Group on several occasions reviewed data "profiles" of programs that would be identified for further review by CPM. Using acceptance rates alone would identify a different set of transplant programs with noticeably different pre-transplant profiles compared to using CPM. For example, based on data from year 2011:
    - One liver program had a slightly above average acceptance rate O/E of 1.01 but a waitlist mortality rate of over 3 times expected (p=0.03). Such a program would be identified by the mortality rate "safety net" component of the CPM approach but not by an acceptance rate only approach.
    - Conversely, several liver programs had low acceptance rates but much lower than expected waitlist mortality rates and would thus not be identified by the CPM approach.
- It is possible for a center that is not adequately meeting the needs of its waitlisted patients to set a significant percentage of its patients to inactive status in order to avoid receiving offers that they have no capacity to accept. This type of manipulation of data would artificially increase their acceptance rates due to a reduced denominator. On the other hand, since the transplant and mortality rate models include both active and inactive patients, these metrics cannot be manipulated in this way. The CPM's use of multiple metrics helps to mitigate against the potential for data manipulation associated with any one metric.
- An analysis completed for the CPM Work Group showed that kidney programs that perform more living donor transplants (as a percentage of their total kidney transplants) tend to be more selective in accepting organ offers, as evidenced by lower (case-mix adjusted) acceptance rates (O/Es) (Additional information available

upon request). In this way, use of acceptance rates alone, which exclusively focus on deceased donor transplantation, might result in unfair pre-transplant performance assessments for programs that rely on a mix of living and deceased donor organs to meet the needs of their waitlisted patients. The CPM, on the other hand, incorporates transplant rates that include both living and deceased donor transplants, as well as acceptance rates.

2. Using transplant rates alone

   During the several year process of developing, scrutinizing, and refining the CPM approach, one alternative suggestion was to use transplant rates alone for evaluating programs' pre-transplant performance. The two high profile cases of waitlist mismanagement, after all, had very low transplant rates. However, this was ultimately not proposed for the following reasons:

   - The 2008 GAO Report[3] emphasized the use of acceptance rates for program monitoring.
   - The OPTN MPSC Process Improvement Working Group's recommendation to use acceptance rates but not as a stand-alone trigger. CPM accomplishes this goal by utilizing acceptance rates in conjunction with mortality and transplant rates to prioritize programs for review.
   - Though CPM would have identified the two high profile programs as "standing out," it was not designed by strictly focusing on those two outliers. The CPM does not rely on the assumption that all future, severe waitlist management problems will manifest the same way as the previous two, where low transplant rates were the leading indicator. Acceptance rates were also extremely low for these programs and may be a leading indicator in some cases.
   - Of the three metrics, acceptance rates are arguably under the most direct influence of transplant programs.
   - The CPM Work Group believed that waitlist mortality rates should play an important role in pre-transplant monitoring, especially for liver programs.

   After the incorporation of a geographic (supply-to-demand) adjustment in the transplant rate model, the use of transplant rates alone for identification of programs was again considered. However, when presented with the option to use only supply-to-demand adjusted transplant rates in April 2013, the CPM Work Group concluded that the composite metric approach was still preferred.

3. Using a transplant rate threshold, a mortality rate threshold, and an acceptance rate threshold independently

   The CPM Work Group was presented with the option of identifying programs based on all of the metrics individually, but instead endorsed the composite metric approach, out of concern that too many programs would be identified using this alternate method. It turns out that setting independent thresholds to identify programs performing 50% "worse" in any of the three metrics (mortality O/E > 1.5, acceptance O/E < 0.67, transplant rate O/E < 0.67, and statistically significant) would have identified an order of magnitude more programs than the CPM approach. Based on an analysis using the July 2012 cohort, 64 kidney and 59 liver programs would have been identified using this alternate approach, a total of 123 programs.

Though these thresholds could be calibrated to identify approximately the same number of programs as CPM, there are a vast number of possible ways to accomplish this. And the CPM Work Group preferred the composite approach since it simplifies the multi-dimensional suite of pre-transplant metrics into a single dimension for monitoring.

4. Using a metric such as Life Years from Listing (LYFL) that combines both pre and post-transplant performance[13]

   Programs may be serving their waitlisted patients equally well in different ways: by performing slightly fewer transplants but maintaining excelling post-transplant outcomes; or by having slightly inferior post-transplant outcomes but performing more transplants. The expected (risk-adjusted) survival of patients after being added to the waitlist may be the same at both programs. LYFL would capture how well transplant programs are serving the patients on their waitlist by measuring patient survival after listing, including both pre and post-transplant survival time; this metric could also be quality-of-life adjusted, for example by discounting survival time after graft failure (e.g., on dialysis).

   Though such a metric may be a very useful and perhaps consumer/patient-friendly way to quantify transplant programs' overall performance, it may not be ideally suited for identifying areas for process improvement. A program with extremely poor post-transplant metrics could have an unextraordinary LYFL if they had very high transplant rates. Conversely, a program with poor pre-transplant performance might be offset in the LYFL by very good post-transplant patient and graft survival metrics. In these ways, the use of a *pre and post*-transplant composite metric such as the LYFL may obscure the need for process improvement in either pre or post-transplant processes.

   The LYFL is also partially redundant with current post-transplant outcomes metrics, so it may not make sense for the MPSC to use both the recently revised Bayesian outcome metrics and LYFL to monitor programs. Still, the LYFL is a metric that deserves further study to determine how best to define it and what purpose it most effectively serves.

5. Using a metric that measures how well hospitals are serving patients with end-stage organ disease in their geographic area, not just those that have been waitlisted.

   The CPM Work Group discussed on several occasions the desirability of measuring performance relative to those patients truly in need, not just those that transplant hospitals choose to add to the waitlist. Expanding the denominator in this way could help alleviate the potential unintended consequence of altered listing practices due to monitoring pre-transplant performance.

   However, the OPTN does not collect data on transplant patients prior to registration on the waitlist. Historically, transplant program performance on patients prior to registration has been outside the purview of the OPTN. Furthermore, even if such data were available and able to be used by the OPTN, it may be difficult to attribute performance to specific transplant programs that serve the same or overlapping populations of end-stage organ failure patients with respect to geographic location (e.g., in the same "health service areas").

[13] Kasiske, B. L., et al. "Report of a consensus conference on transplant program quality and surveillance." *American Journal of Transplantation* 12.8 (2012): 1988-1996.

6. Applying a statistical process control (SPC) technique such as CUSUM in lieu of developing a cohort-based pre-transplant metric for identifying programs.

   An SPC technique such as CUSUM (Cumulative Sum) may actually be more adept than CPM at rapidly detecting sudden disruptions in a transplant program's ability to serve its waitlisted patients. The SRTR contractor has already developed post-transplant CUSUM charts to help programs identify potentially concerning trends in patient and graft outcomes. HRSA and both the OPTN and SRTR contractors have discussed the possibility of applying the CUSUM methodology to pre-transplant metrics as well.

   However, the CPM Work Group considers CUSUM and CPM to be complementary tools, as opposed to one being a potential replacement for the other, just as post-transplant CUSUM charts[14,15] are complementary to post-transplant O/E's. Post-transplant CUSUM charts are being used strictly for transplant programs' self-improvement (QAPI) efforts, not for OPTN/MPSC oversight purposes. Pre-transplant CUSUM charts could potentially be used in the same way. They would not alleviate the need for a cohort-based pre-transplant metric like CPM, but rather serve in a complementary role to help alert programs to potentially concerning trends in pre-transplant performance. Additional work is needed in this area.

Method for 'Shrinking' O/E Ratios: Approximation to Empirical Bayes/BLUP

Rationale for using Empirical Bayes methodology

During the initial attempts to combine O/E ratios, it became clear that accounting for the variability due to small sample sizes would be critical. Failing to address statistical uncertainty would lead to "small sample false positives," where the programs having the most aberrant composite metric values were those with the smallest sample sizes, and thus those with the least empirical evidence of a potential problem. These false positives would obscure the metric's ability to identify true positives, programs with sufficient evidence to suggest a pre-transplant performance issue exists and who actually need to implement improvement measures.

Use of p-values to address sampling variability was considered. For example, all O/E ratios not statistically different from 1.0 could be set to 1.0. However, this approach would be highly reliant on the arbitrary significance level threshold of 0.05 (or other chosen alpha level). For example, a program with a transplant rate O/E of 2.50 (p=0.04) would have 2.5 used in the composite metric, whereas a program with transplant rate O/E of 2.5 (p=0.06) would have a 1.0. Furthermore, this approach forces an unsatisfactory binary decision – either use the nominal O/E (if $p<0.05$) or use 1.0 (if $p>=0.05$) – when in reality a better estimate of a program's true underlying performance may lie somewhere in the middle. For developing this composite metric, effective *estimation* was paramount and far more relevant than *hypothesis testing*.

Consequently, the Empirical Bayes estimation methodology – a.k.a., best linear unbiased prediction (BLUP) – was a natural choice for accounting for sampling variation in the O/E ratios

[14] Biswas, Pinaki, and John D. Kalbfleisch. "A risk-adjusted CUSUM in continuous time based on the Cox model." *Statistics in medicine* 27.17 (2008): 3382-3406.

15 Axelrod, D. A., et al. "Transplant Center Quality Assessment Using a Continuously Updatable, Risk-Adjusted Technique (CUSUM)." American journal of transplantation 6.2 (2006): 313-323.

before combining them. This approach is derived from a "random effects" (hierarchical) model, with patient-level (or organ offer-level) data contained within transplant hospitals. By estimating the random effect for each program, the result is a weighted average of the program's observed performance in a particular metric and the overall national average performance.

The approximation to the Empirical Bayes method results in a weighted average of the program's observed O/E ratio and the overall national average of 1.0, essentially "shrinking" the program's O/E toward 1.0. Conceptually, this approach is "Bayesian" because it starts with the proposition that a transplant program is no different from the rest of the nation (O/E=1.0), and then modifies that proposition based on the strength of evidence underlying the program's O/E ratio. It can also be thought of as an example of the "regression to the mean" phenomenon[16], where future values tend to be more similar to the long-run average than to very recent results. Programs with large sample sizes (small amount of statistical uncertainty in the O/E) will have a resulting value very close to their nominal O/E value (minimal "shrinkage"). Conversely, O/E's for programs with small sample sizes will be pulled closer to 1.0, reflecting the uncertainty in their observed performance.

It is highly unlikely that a program with a waitlist mortality rate O/E of 8.5, based on one patient death, is actually 8.5 times worse than the national average in terms of mitigating death on the waitlist. A better estimate of this program's true performance is somewhere closer to 1.0, perhaps just slightly above 1.0. The Empirical Bayes (BLUP) methodology recognizes that the 8.5 is not a realistic estimate, even if it happens to be statistically significantly different from 1.0. This methodology has been shown to perform better at estimating true underlying performance than using the nominal center effect estimates and has been used extensively in estimating institutional performance in healthcare.[17,18,19,20] Using shrinkage estimation for more reliable estimation of institution performance was also a recommendation from the Committee of Presidents of Statistical Societies.[21]

The CPM Work Group reviewed data on CPM by size of transplant program, as measured by number of waitlist candidates. Results showed that the percentage of programs with CPM > 1.5 was statistically no different for programs with 10-49 patients, 50-99, 100-249, 250-499, and 500+, suggesting that the CPM methodology is not biased toward small, medium, or large programs. However, extremely small programs (<10 candidates) tend to have CPMs close to 1.0; none of these programs had CPM > 1.5 due to the absence of strong evidence suggesting true deviance in pre-transplant performance.

Addition of "limited translation rules"

One weakness of the Empirical Bayes (BLUP) methodology is the potential for "overshrinkage." This phenomenon can occur when a program with truly aberrant performance is assumed, as in Empirical Bayes methodology, to be part of the same bell-shaped distribution as all other

16 Stigler, Stephen M. "Regression towards the mean, historically considered." Statistical methods in medical research 6.2 (1997): 103-114.

18 Thomas, N., Longford, N. T. and Rolph, J. E. (1994), Empirical Bayes methods for estimating hospital-specific mortality rates. Statist. Med., 13: 889–903. doi: 10.1002/sim.4780130902

19 Christiansen CL, Morris CN. Improving the Statistical Approach to Health Care Provider Profiling. Ann Intern Med. 1997;127:764-768. doi:10.7326/0003-4819-127-8_Part_2-199710151-00065

20 Efron, Bradley, and Carl N. Morris. *Stein's paradox in statistics*. WH Freeman, 1977.

21 "Statistical Issues in Assessing Hospital Performance," Commissioned by the Committee of Presidents of Statistical Societies (COPSS), 2012.

programs. Since a key purpose of the CPM is to identify outlying performance, the possibility of overshrinkage was a valid concern.

To mitigate against overshrinkage, "limited translation rules"[22] are applied. The limited translation rule implemented in the CPM methodology is that shrinkage is constrained to extend no further than the 95% confidence limits for the O/E ratio. If shrinkage would shift an O/E ratio closer to 1.0 than either the upper or lower confidence limit, the modified O/E value is set equal to the confidence limit instead.

Approximation to empirical Bayes/BLUP method for 'shrinking' O/E ratios

The "shrunken" O/E's are derived by the following formula, which can be thought of as a weighted average between the program's O/E ratio and the national average, or 1.0, on a natural logarithm scale:

$$(1) \quad Shrunken\ (O/E) = \frac{\sigma_D^2}{(\sigma_D^2 + \sigma_r^2)} * \ln(O/E) + \frac{\sigma_r^2}{(\sigma_D^2 + \sigma_r^2)} * \ln(1.0)$$

The term $\frac{\sigma_D^2}{(\sigma_D^2+\sigma_r^2)}$ is the weight associated with the program's observed O/E ratio, while $\frac{\sigma_r^2}{(\sigma_D^2 + \sigma_r^2)}$ is the weight associated with the central value of 1.0. Together, these two weights sum to 1, or 100%. Since ln (1.0) is zero, the second half of the formula collapses and what remains is simply

$$(2) \quad Shrunken\ (O/E) = \frac{\sigma_D^2}{(\sigma_D^2 + \sigma_r^2)} * \ln(O/E)$$

σ^2_D represents an estimate of the variance among programs (or, "program-to-program" variance) in the metric of interest, either transplant rate, mortality rate, or acceptance rate. σ^2_r represents an estimate of the variance associated with the particular program's metric of interest. The higher the variance in the program's metric, the lower the weight and hence the greater the shrinkage. The greater the program-to-program variability, the higher the weight and hence less shrinkage.

This formula is actually derived as the best linear unbiased predictor (BLUP) from a random effects model where the response variable is normally distributed. It is also commonly referred to as the empirical Bayes estimator. This formula was adapted to accommodate the binomial (acceptance rates) and poisson-distributed (mortality and transplant rates) metrics that comprise the CPM, as follows:

Binomial case (acceptance rates):

- ✓ Program-specific variance: σ^2_r calculated as p*(1-p)/N, where
  - p is the overall, national average acceptance rate across all programs
  - N is the number of offers received by this program
- ✓ Program-to-program variance: σ^2_d is calculated as follows
  - First, the estimated acceptance rate for each program *assuming they all had the same, average case-mix of offers and candidates* is computed.

[22] Efron, Bradley, and Carl Morris. "Limiting the risk of Bayes and empirical Bayes estimators—Part II: The empirical Bayes case." *Journal of the American Statistical Association* 67.337 (1972): 130-139.

- This is done by starting with the overall odds of acceptance across all programs and multiplying by each program's acceptance rate O/E ratio.
- These odds of acceptance for each program are then converted back to acceptance probabilities as follows: probability=odds/(1 + odds).
- This results in a distribution of acceptance rates among programs with case mix differences removed, to isolate program-to-program differences.
- The sample-weighted variance of these acceptance rates is then calculated, with the weights equal to the number of offers associated with each rate, to obtain σ^2_d.

✓ The acceptance rate shrinkage weight for each program is calculated as a function of σ^2_r and σ^2_d, as shown in (2) above.

✓ If shrinkage is found to exceed either the upper or lower 95% confidence limit, the value is set to the respective limit, to avoid potentially overshrinking. See "Addition of Limited Translation Rules" above.

✓ Shrunken acceptance rate O/Es are expressed in the probability ratio (or relative risk) scale – *not the odds ratio scale* – for inclusion in the CPM, to parallel mortality and transplant rate O/Es, which are expressed on the hazard ratio scale.

Poisson case (mortality and transplant rates):

✓ Program-specific variance: σ^2_r calculated as $(1/K^2)*\lambda$, where
- K is the number of person-years for the specific program
- λ is the overall, national average mortality (or transplant) rate across all programs per person-year, multiplied by K
- σ^2_r simplifies to the overall national mortality (or transplant) rate per person year divided by the number of person-years for the specific program.
- This is derived from Poisson model conditional on the (fixed) number of person-years observed for each center.

✓ Program-to-program variance: σ^2_d is calculated as follows
- First, the estimated mortality (or transplant) rate for each program *assuming they all had the same, average case-mix of candidates* is computed.
- This is done by starting with the overall mortality (or transplant) rate across all programs and multiplying by each program's mortality (or transplant) rate O/E ratio.
- This results in a distribution of mortality (or transplant) rates among programs with case mix differences removed, to isolate program-to-program differences.
- The sample-weighted variance of these mortality (or transplant) rates is then calculated, with the weights equal to the number of person-years associated with each rate, to obtain σ^2_d.

✓ The mortality (or transplant) rate shrinkage weight for each program is calculated as a function of σ^2_r and σ^2_d, as shown in (2) above.

✓ If shrinkage is found to exceed either the upper or lower 95% confidence limit, the value is set to the respective limit, to avoid potentially overshrinking. See "Addition of Limited Translation Rules" above.

Instead of adapting the normal-theory BLUP formula to accommodate acceptance rates (binomial) and mortality and transplant rates (Poisson), an alternative would be to simply estimate the program-specific odds ratios or hazard ratios from a random effects estimation in a mixed-effects binary or Cox regression model. This approach, however, was outside the purview and charge given to the OPTN, which was to identify ways to use the already available risk-adjusted

metrics produced by the SRTR contractor to develop a new MPSC tool for pre-transplant performance monitoring. A future enhancement to the CPM could include adoption of this alternate approach, where the shrunken O/E ratios (center effects) come directly as output from a multivariable model estimation procedure.

Another possible future enhancement is to adopt a more explicitly Bayesian approach using either a Gamma or Beta prior. The distribution parameters of the prior would be either selected to achieve the desired shrinkage (as in the recently adopted OPTN Bayesian methods for post-transplant outcomes[23]), or empirically derived in order to maintain the spirit of the approach currently used in the CPM.

Example CPM Calculation

Below is an example CPM calculation for a medium-sized liver program WXYZ-TX1.

Pre-transplant metrics for WXYZ-TX1, which had a waitlist size of 100-200 liver patients:

- Waitlist mortality rate O/E = 1.11
- Geography-adjusted transplant rate O/E = 0.64
- Acceptance rate O/E = 0.80

Step 1. Apply logarithmic transformation of O/E ratios (for symmetry)

Mortality rates: ln(1.11) = 0.104
Transplant rates: ln(0.64) = -0.446
Acceptance rates: ln(0.80) = -0.223

Step 2. Apply negative sign for transplant and acceptance rates (directional consistency)

Mortality rates: 0.104 (no change)
Transplant rates: (-1) • (-0.446) = 0.446
Acceptance rates: (-1) • (-0.223) = 0.223

Step 3. Account for statistical uncertainty due to finite sample sizes (Empirical Bayes method)

"Shrunken" mortality rate O/E_{ln} = (0.104) • (mortality shrinkage weight) = (0.104) • (0.796) = 0.083
"Shrunken" transplant rate O/E_{ln} = (0.446) • (transplant shrinkage weight) = (0.446) • (0.920) = 0.410
"Shrunken" acceptance. rate O/E_{ln} = (0.223) • (acc. shrinkage weight) = (0.223) • (0.857) = 0.191

Shrinkage weights are program-specific and depend on the sample size (number of person-years on the waitlist or number of offers received) as well as the overall program-to-program variability in the specific metric. See "Approximation to Empirical Bayes Method for 'Shrinking' O/E Ratios" section of the appendix for more detail on this methodology.

In Step 3, shrinkage is constrained (per "limited translation rules") so as not to extend beyond the 95% confidence limits for the original O/E ratio. If (on the O/E scale) the shrinkage extends

[23] Salkowski, N., et al. "Bayesian methods for assessing transplant program performance." *American Journal of Transplantation* 14.6 (2014): 1271-1276.

beyond either the lower or upper limit, then the value is set to the natural logarithm of the respective limit.

Step 4. Combine into a single metric by applying component weights (composite approach)

$CPM_{log\ scale}$ = (0.50) • (0.083) + (0.25) • (0.410) + (0.25) • (0.191) = 0.192

For kidney programs, note that the component weights would be 0.00, 0.50, and 0.50 for mortality, transplant, and acceptance rates, respectively.

Step 5. Apply antilog function (return to O/E scale)

CPM = exp($CPM_{log\ scale}$) = **1.21**

This program has an aggregate, pre-transplant performance metric 21% higher than expected. CPM values greater than one are generally associated with lower acceptance rates, lower transplant rates, and higher waitlist mortality rates.

CPM Calculation: Exclusions and Special Cases

Programs excluded from CPM calculation

Programs with zero person-years for both mortality rate and transplant rate calculations are excluded from CPM calculations. Also excluded are programs that have already withdrawn (either voluntarily or involuntarily) before the start of the one-year cohort period.

Zero deaths, acceptances, or transplants

In cases where a program has zero deaths, zero acceptances, or zero transplants, formula (1) above cannot be computed since the logarithm of zero is undefined. In these circumstances, formula (1) is adapted by applying the shrinkage weights on the linear scale instead of the log scale. This leads to a weighted average between 0 and 1, which reduces to (1.0)*($\frac{\sigma_r^2}{(\sigma_D^2+\sigma_r^2)}$) as the estimated shrunken O/E ratio.

Zero offers received

If zero offers were received, the acceptance rate O/E is set to 1.0.

At-a-Glance

Proposal to Reduce the Reporting Requirements for the Deceased Donor Registration Form

- **Affected/Proposed Policy:** Policy 18.1 (Data Submission Requirements)

- **Organ Procurement Organization Committee**

  Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased donors. This must be completed within 30 days after the deceased donor feedback form is submitted. Due to inconsistent data reporting on those potential donors that do not proceed to donation, the OPO Committee is proposing that the requirement to complete the DDR for non-donors be removed from policy. The goal of this proposal is to reduce the data reporting requirements for "non-donors" by only requiring the completion of the DDR on actual donors.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  PR/Public Education Staff
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  This proposal does not impact potential candidates.

- **Compliance with OPTN Strategic Plan and Final Rule**
  The proposal promotes the OPTN's Strategic Plan "promoting the efficient management of the OPTN" by eliminating the collection of unnecessary data elements.

Proposal to Reduce the Reporting Requirements for the Deceased Donor Registration Form

Affected/Proposed Policy: Policy 18.1 (Data Submission Requirements)

Organ Procurement Organization Committee

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased donors. This must be completed within 30 days after the deceased donor feedback form is submitted. Due to inconsistent data reporting on those potential donors that do not proceed to donation, the OPO Committee is proposing that the requirement to complete the DDR for non-donors be removed from policy. The goal of this proposal is to reduce the data reporting requirements for "non-donors" by only requiring the completion of the DDR on actual donors.

Background and Significance of the Proposal:

Policy 18.1 requires members to report data to the OPTN using standardized electronic forms. Table 18.1 lists the member responsibilites and timeframe for each of the data forms, including the deceased donor registration and donor feedback form. Currently, the host OPO is responsible for completing the deceased donor registration form for all deceased donors and authorized but not recovered potential deceased donors. However, the DDR was never intended to be used for "non-donors." Prior to December 2001, a cadaver donor referral form was available for members. This form was generated only for donors that were added to the UNOS database through UNet and ultimately did not become an organ donor. The data collected on this form included demographic information, cause of death, mechanism of death, circumstances of death, suitability for procurement and consent information. One reason for the elimination of this form is the inconsistencies in reporting by the OPOs on this form. However, the requirement that OPOs report on all donors and authorized but not recovered potential donors did not change. This required OPOs to complete the DDR even for those cases that did not go on to donation. Much of the DDR is only applicable to an actual donor and therefore much of the data that are submitted on non-donors is reported as unknown.

The current process for submitting donor information is outlined below:

- OPO adds a donor or potential donor into DonorNet®.
- If the OPO does not request or obtain authorization for organ donation, the OPO marks the record as "Referral Only" and has completed their data submission requirements.
- If authorization for organ donation is obtained, the OPO then fills out the Donor Organ Disposition (Feedback) for each organ (recovered or not).
- Once feedback is complete and reconciled with the transplant center, the DDR is generated. The OPO has 30 days to complete the DDR.
- There is basic information on imminent and eligible deaths that is collected on the death notification report form.

The Committee discussed the purpose of collecting data on authorized but not recovered donors or those for whom authorization was not obtained. Because there is limited information available

on non-donors there is no need to collect it on a form that was designed for deceased donor information. The Committee also discussed the purpose of collecting information on decedents from whom organs are recovered for reasons other than transplant. The Committee agreed that only information on individuals from whom at least one organ was recovered for the purpose of transplantation should be collected.

The Committee agreed to the following:

- OPOs should only be required to complete the deceased donor registration (DDR) form on actual donors, defined as having at least one organ recovered for the purpose of transplantation.
- Make the following change to the deceased donor definition: An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.

Supporting Evidence and/or Modeling:

The Committee analyzed the number of Deceased Donor Registration (DDR) forms that were submitted by the OPOs to determine those that were submitted for actual donor cases and those that were submitted for non-donor cases. The Committee looked at DDRs submitted to the OPTN from 2010 through 2013. The Committee wanted to know what percentage of DDRs submitted by an OPO was for non-donors. Below is a table that groups the OPOs by the percentage of non-donor DDRs they submitted.

Percentage of DDRs Submitted for Non-Donors	Number of OPOs
< 1%	16
1% to < 5%	9
5% to < 10%	7
10% to < 15%	13
15% to < 20%	9
20% - 23%	4

The Committee determined that many OPOs are not filling out the DDR for their non-donors. The Committee also noted that many of the fields on the DDR cannot be filled out for these non-donors.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

No known impact to specific patient candidates.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

The proposal promotes the OPTN's Strategic Plan "promoting the efficient management of the OPTN" by eliminating the collection of unnecessary data elements.

Plan for Evaluating the Proposal:

This proposal will not require evaluation since it eliminates unnecessary data collection.

Additional Data Collection:

This proposal does not require additional data collection; instead, it will decrease the data collection burden on members.

Expected Implementation Plan:

If public comment is favorable, the proposal may be presented at the OPTN/UNOS Board of Directors meeting in June 2015 and effective upon completion of programming.

As mentioned earlier in the proposal, OPOs have the option of clicking "Referral Only" in the Donor Organ Disposition (Feedback). Referral is defined as when no consent was requested or obtained. One consideration for implementation is to change "Referral Only" to "No organs were recovered for the purpose of transplantation." This will provide OPOs with the opportunity to suspend the DDR for those potential donors that do not proceed to donate any organs.

Communication and Education Plan:

Upon Board approval, communications vehicles can be used to inform transplant professionals (specifically OPOs) about the policy modifications regarding the Deceased Donor Registration (DDR) form, the associated requirement change and definition changes. OPOs already record the information in UNet^{SM} via the DDR, so there is no substantive change in practice. This policy modification would not be significant enough to require extensive notification, UNet^{SM} system training, or special instructional sessions. There is actually a reduction in OPO effort because reporting requirements for non-donors are being removed from policy. There are no actual system changes associated with this effort, only updates to the online help documentation are needed.

The first notification of this change will be sent to members through the policy notice 30 days after the Board meeting and a link to the policy notice will be included in the Transplant Pro e-newsletter. Additional communications will be provided, if necessary.

Compliance Monitoring:

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested.

Policy Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

Table 18-1: Data Submission Requirements

The following member:	***Must submit the following materials to the OPTN Contractor:***	***Within:***	***For the following groups:***
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30-days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30-days after the transplant hospital removes the candidate from the waiting list because of transplant • 30-days after the transplant hospital submits the *recipient feedback*	For each transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30-days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30-days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30-days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	*Deceased donor feedback*	5 business days after the procurement date	For all deceased donors

The following member:	*Must submit the following materials to the OPTN Contractor:*	*Within:*	*For the following groups:*
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors ~~and authorized but not recovered potential deceased donors~~
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	1. 30-days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure 2. 14-days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60-days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60-days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24-hours after the transplant	For each recipient transplanted by the hospital

The following member:	*Must submit the following materials to the OPTN Contractor:*	*Within:*	*For the following groups:*
Transplant hospitals	*Recipient malignancy* (PTM)	30-days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	For each recipient, with a reported malignancy, that is followed by the hospital
Transplant hospitals	*Transplant candidate registration* (TCR)	30-days after the transplant hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted by the hospital

1.2 Definitions

Deceased donor
An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.

At-a-Glance

Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

- **Affected Policies:** Policy 2.7 (HIV Screening of Potential Deceased Donors), Policy 15 (Identification of Transmissible Diseases), and Policy 16.7.B (Vessel Storage)

- **Organ Procurement Organization Committee**

  Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act, enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to concurrently amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  Over the past several years there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013. There are likely many more patients awaiting transplants. Boyarsky et al determined that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year[1].

- **Compliance with OPTN Strategic Plan and Final Rule**
  This proposal supports the OPTN's Strategic Plan by increasing the number of transplants and increasing access to transplants. This proposal will also address future changes to the Final Rule that will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organs.

Proposal to Address the Requirements Outlined in the HIV Organ Policy Equity Act

Affected Policies: Policy 2.7 (HIV Screening of Potential Deceased Donors), Policy 15 (Identification of Transmissible Diseases), and Policy 16.7.B (Vessel Storage)

Organ Procurement Organization Committee

Public comment response period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

Current federal rules and OPTN policy prohibit the recovery and transplantation of organs from deceased donors infected with the human immunodeficiency virus (HIV). The HIV Organ Policy Equity Act, enacted on November 21, 2013, will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ. The goal of this proposal is to concurrently amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS).

Background and Significance of the Proposal:

The HIV Organ Policy Equity Act outlines future changes to the Final Rule and contains a schedule of deliverable deadlines. The initial requirements are:

- By November 21, 2015, the Secretary of HHS must develop and publish criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organ.
- By November 21, 2015, the Secretary of HHS must revise the section of the OPTN Final Rule (42 CFR 121.6) that presently requires the OPTN to adopt and use standards to prevent the recovery of HIV-infected organs.
- By November 21, 2015, to the extent determined by the Secretary to be necessary to allow the conduct of research, the OPTN shall revise standards of quality (i.e. policies) for acquisition and transportation of donated organs infected with HIV in accordance with the criteria developed by the Secretary as described above. This must begin concurrently with the Secretary's development of criteria for research in order to meet the two year deadline.

By November 21, 2017, and each year thereafter the Secretary of HHS will**:**

- Review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards;
- Determine if participation in clinical research, as a requirement for such transplants, is no longer warranted;
- Review the results of scientific research in conjunction with the OPTN to determine whether the results warrant revision of the standards of quality with respect to donated organs infected with HIV and with respect to the safety of transplanting an organ with a particular strain of HIV into a recipient with a different strain of HIV;

[1] Boyarsky, B. J., Hall, E. C., Singer, A. L., Montgomery, R. A., Gebo, K. A. and Segev, D. L. (2011), Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States. American Journal of Transplantation, 11: 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.x

- Determine necessary conduct of research in accordance with the criteria developed;
- Determine if results warrant revision of the standards of quality; and
- Direct the OPTN to revise such OPTN standards in a way that ensures the changes will not reduce the safety of organ transplantation.

OPOs will remain responsible for "arranging for testing with respect to identifying organs that are infected with human immunodeficiency virus (HIV)" Per 42 USC 273(b)(3)(C)

Formation of a joint work group

The OPTN formed a joint work group with representation from the Organ Procurement Organization (OPO) Committee, Operations and Safety Committee, Ad Hoc Disease Transmission Advisory Committee (DTAC), SRTR, and HRSA. The initial conference call was held on January 31, 2014, during which four subgroups were formed to address policy, patient safety, allocation, and labeling/transport. Each of these subgroups were assigned policies to determine if changes are required to address the use of HIV infected organs as well as identifying other issues that could be impacted by the new law.

The four subgroups met individually by conference call and provided initial recommendations to the full work group on April 2, 2014. The subgroups identified the key policies that need to be modified in order to allow for the recovery and transplantation of HIV-infected organs. The work group also determined that the current prohibition on the storage of hepatitis C antibody positive and hepatitis B surface antigen positive (HBsAg) extra vessels should be extended to HIV-infected extra vessels. During the review of the policies, several minor language issues were identified such as numerous references to serology results and the use of informed authorization instead of consent. These will be addressed during a future proposal or other means outside the scope of this project.

The work group discussed the operational issues that will need to be addressed once more information about the research protocols becomes available from the National Institutes of Health (NIH), the organization that is developing the criteria for the research study. Overall, the work group agreed that current testing for infectious diseases provides the appropriate safeguards to prevent disease transmission. However, unlike current practice, organs known to be infected with HIV will now be allocated and appropriate safeguards need to be in place to ensure that HIV-infected organs get allocated only to those HIV-positive candidates willing to accept the organ.

Future proposal

The work group will continue to evaluate policy and operational issues in preparation for the next public comment period in January 2015. The next proposal will address informed consent, living donation issues, patient safety, and other issues identified by the work group.

Supporting Evidence and/or Modeling:

The OPTN does not currently collect the HIV status of candidates on the waiting list. For this reason, the exact number of potential candidates that could benefit from this policy change is unknown. However, over the past several years there has been a steady increase in the number of transplants performed each year for reported HIV positive recipients, from 15 in 2001 to 137 in 2013. There are likely many more patients awaiting transplants. Boyarsky et al maintain that

annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year[1].

Expected Impact on Living Donors or Living Donation:

It is anticipated that living donors will be included in the research protocols being developed by the NIH. However, before removing HIV from the exclusion criteria listed in Table 14-2 (Requirements for Living Kidney Donor Medical Evaluations) the group will seek input from the Living Donor Committee and the transplant community.

Expected Impact on Specific Patient Populations:

This proposal will lead to the increased availability of organs for candidates with HIV. Boyarsky et al maintain that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year[2].

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

This proposal supports the OPTN's Strategic Plan by increasing the number of transplants and increasing access to transplants. This proposal will also address future changes to the Final Rule that will allow for the development and publication of criteria for the conduct of research relating to transplantation of organs from donors infected with HIV into individuals who are infected with HIV before receiving such organs.

Plan for Evaluating the Proposal:

This proposal is the first step to amend OPTN policies to allow members to participate in the research study in accordance with upcoming changes to the Final Rule and criteria developed by the Secretary of Health and Human Services (HHS). According to the HIV Organ Policy Equity Act, the Secretary of HHS will work in conjunction with the OPTN to review the results of scientific research by November 21, 2017.

Six months after the first HIV positive donor transplant is performed as part of the research study the committee will request the following information:

- The number of HIV positive donor transplants performed by organ type
- The number of transplant programs approved, and the number performing these transplants
- The number of OPOs with at least one HIV positive deceased donor recovered
- The number of candidates indicated as willing to accept an organ from an HIV positive donor
- The number of unintended HIV donor transmissions.

These data will be updated twice a year for at least three years after the first transplant is performed. Once enough HIV positive donor transplants have been performed, Kaplan-Meier

[1] Boyarsky, B. J., Hall, E. C., Singer, A. L., Montgomery, R. A., Gebo, K. A. and Segev, D. L. (2011), Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States. American Journal of Transplantation, 11: 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.x

patient and graft survival rates at 6 months and one year post-transplant will be included along with the other data points.

Additional evaluation planning will be required as more information is known about the research protocols.

Additional Data Collection:

At this time it is unknown what additional data elements will be required for participation in the research study. When these become available these will be addressed in a future proposal.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect concurrent with the implementation of the HOPE Act (November, 2015).

This proposal is only one step in changing policy to allow for the recovery and transplantation of HIV-infected organs. Once HHS publishes the research protocols required by the HOPE Act, the OPTN workgroup will discuss whether additional policy modifications are necessary. Those changes will be released for public comment in 2015.

Communication and Education Plan:

The proposal would apply to hospitals performing HIV positive transplants and OPOs that would recover HIV positive organs. Communication and education efforts would thus focus on the specific details of the policy modifications and support members may need to revise their processes.

Information about the policy modifications would be included in an effort to provide communication and instruction to members, with emphasis on impacted practices at transplant programs and OPOs.

In addition, notification of the policy modifications would be included in the following routine communication vehicles:

- Policy notice
- System notice
- Member e-newsletter/member communicaitons
- Communication to appropriate listservs

Compliance Monitoring:

The following changes may apply to existing routine monitoring of OPTN members:

Policy 2.7 *HIV Screening of Potential Deceased Donors*
At OPOs, site surveyors will review a sample of deceased donor records for the following documentation:

- The results of all HIV testing performed on the donor

Policy 16.7.B *Vessel Storage*
At transplant hospitals, site surveyors will review the transplant hospital's internal policies, procedures, and/or protocols and/or interview key clinical personnel to verify that they address:

- That HIV+, HCV+ and HbSAg+ vessels are not stored for later use

The following new routine monitoring may apply to OPTN members:

Policy 15.3 *Recovery and Transplantation of HIV-infected Organs*
At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The recipient of any organ from a donor infected with HIV was known to be infected with HIV prior to transplant

OPTN staff will continue to review all deceased donor match runs resulting in a transplanted organ to ensure that allocation was carried out according to OPTN policy. Staff will request evidence of participation in an institutional review board-approved research protocol for recovering organs from donors known to be infected with HIV from any transplant program that has transplanted an organ from a donor known to be infected with HIV.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

2.7 HIV Screening of Potential Deceased Donors

~~Members may not participate in the recovery or transplantation of organs from deceased donors known to be infected with HIV. Members may only recover organs if the laboratory data, medical history, and behavioral history indicate that the donor is not HIV infected.~~

The host OPO must accurately document HIV test results for every deceased donor. All deceased donors must be tested for HIV according to *Policy 2.9: Required Deceased Donor Infectious Disease Testing*.

The host OPO must report the results of all HIV tests it performs directly to all receiving OPOs and transplant programs.

Policy 15: ~~Identification of~~ Transmissible Diseases

15.3 Recovery and Transplantation of HIV-infected Organs

Members may recover and transplant organs known to be infected with human immunodeficiency virus (HIV) only if *all* of the following are true:

- The potential recipient is known to be HIV-infected before receiving the organ

- The transplant hospital is participating in an institutional review board approved research protocol that meets the requirements in the Final Rule, 42 CFR 121 *et seq*., regarding the recovery of organs from individuals known to be infected with HIV.

~~15.3~~15.4 Informed Consent of Transmissible Disease Risk

Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.

16.7.B Vessel Storage

Transplant hospitals may not store for later use any HIV positive, hepatitis C antibody positive (HCV) or hepatitis B surface antigen positive (HBsAg) extra vessels. If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

The Transplant hospital must designate a person to do *all* of the following:

1. Monitor and maintain all records relating to the use and management of vessels
2. Monitor the refrigerator where the vessels are stored
3. Destroy expired vessels
4. Notify the OPTN

Additionally, the transplant hospitals must do *all* of the following:

1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution
2. Package and label vessels as required by *Policy 16.4: Packaging and Labeling*
3. Store vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
4. Monitor vessels daily with documented security and temperature checks
5. Destroy unused vessels within 14 days after the recovery date
6. Maintain a log of stored vessels
7. Have accessible at all times the vessel deceased donor information for the transplant surgeon prior to using the vessels in any recipient other than the originally intended recipient

At-a-Glance

Proposal to Allow Collective Patient and Wait Time Transfers

- **Affected/Proposed Policies and Bylaws: Policy 3.6.C (Waiting Time Transfers); Policy 3.8 (New: Collective Patient Transfers); Bylaws K.6 (Transferred Candidates Waiting Time)**

- **Operations and Safety**

  This proposal provides a process to transfer patients and their wait time collectively when a transplant program stops performing organ transplants due to one of the following:

  - long-term inactivity
  - withdrawal of membership
  - termination of membership

  Current policy and bylaws outline a process by which a registered individual can transfer primary waiting time. Processing large groups of patients who must transfer when a program stops performing transplants for an extended period is currently challenging. These situations could be handled safely and efficiently through a collective transfer process. This proposal outlines requirements to allow the OPTN to transfer patients collectively.

- **Affected Groups**
  Transplant Administrators
  Transplant Coordinators
  Transplant Program Directors
  Organ Candidates

- **Number of Potential Candidates Affected**
  All listed transplant candidates may be affected if their transplant program enters into long-term inactivity, withdraws OPTN membership, or experiences OPTN membership termination. From 2011-2013, 45 programs were withdrawn, with a total of 1,524 candidates on their wait lists within the 180 days prior to program closure.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal supports the following strategic plan goals:

  1. Promote transplant patient safety
  2. Promote efficient management of the OPTN

  The proposal promotes transplant patient safety, as all information will be transferred electronically reducing possibilities for data entry or transcription errors if records are re-entered or manually adjusted. The proposal promotes efficient management of the OPTN by converting an individual process to a collective process, reducing opportunity for lost paperwork and transfer processing time, and restoring opportunity for transplant in a timely manner.

- **Specific Requests for Comment**
    1. Should a deadline be proposed to complete full evaluations following a collective transfer?
    2. Should post-transfer reporting be done every 90 days until the post-transfer evaluation plan is complete?
    3. Should a new post-transfer evaluation plan be developed if circumstances change?
    4. What are expectations about the receiving transplant program communicating active versus inactive status to candidates?

Proposal to Allow Collective Patient and Wait Time Transfers

Affected/Proposed Policies and Bylaws: Policy 3.6.C (Waiting Time Transfers); Policy 3.8 (New: Collective Patient Transfers); Bylaws K.6 (Transferred Candidates Waiting Time)

Operations and Safety Committee

Public Comment Response Period: September 29, 2014 – December 5, 2014

Summary and Goals of the Proposal:

This proposal provides a process to transfer patients and their wait time collectively when a transplant program stops performing organ transplants due to a status change to one of the following:

- long-term inactivity
- withdrawal of membership
- termination of membership

Current policy and bylaws outline a process by which a registered individual can transfer primary waiting time. Processing large groups of patients who must transfer when a program stops performing transplants for an extended period is currently challenging. These situations could be handled safely and efficiently through a collective transfer process. This proposal outlines requirements to allow the OPTN to transfer patients collectively.

Background and Significance of the Proposal:

Current OPTN Policy 3.6.C (Waiting Time Transfers) provides a specific mechanism using the individual Wait Time Transfer Form when a transplant candidate wishes to transfer primary waiting time from one transplant hospital to another. These forms are completed by either transplant hospital and sent to the OPTN Contractor. The OPTN Contractor processes these forms manually. Each transfer takes up to 30 minutes to complete. When a transplant hospital enters long-term inactivity or closes, significant numbers of patients might need to be transferred within a short time frame. Using the individual process to complete this task creates a burden on transplant programs and a data entry backlog with potential for delayed entry, missing patient forms, and delayed transplant opportunities.

This proposal would create an official process where the closing center and accepting center(s) would sign an agreement and provide the OPTN with a list(s) of patients to be transferred. The process would keep all current required patient notifications in place and would not bypass providing transfer choices.

The OPTN Contractor will:

- Review the patient transfer list(s)
- Provide notification to the hospitals once the collective transfer(s) has been completed
- Provide the accepting hospital with a list of patients transferred

The receiving program will:

- Assume management of the transferred patients without any record modifications
- Assume other applicable patient notification and regulatory requirements.
- Designate the appropriate patient status according to their protocols and selection criteria.

The proposal would authorize the OPTN to complete collective transfers if a transplant program no longer qualifies as a designated transplant program prior to fulfilling the outlined requirements and the accepting transplant program requests completion of the transfer.

This proposal was developed under leadership of the Operations and Safety Committee. The workgroup addressing this issue included representatives from the Transplant Administrators, Transplant Coordinators, and Patient Affairs Committees. In addition, UNOS staff, which provide assistance during program closures, participated in the group. This work group also developed a resource tool kit to help answer common questions, share effective practices, and highlight current requirements when transplant programs inactivate long-term or close.

Alternatives considered would be to 1) continue using the individual wait time transfer process in large volume situations or 2) to transfer patients collectively but place them in an inactive status until evaluation is completed at the accepting transplant program. The current individual wait time process will continue to be used if this proposal is not approved. Placing a patient into an inactive status for transfer purposes was debated but not considered an appropriate function of the OPTN. The proposal does place responsibility to manage the patient's status from the effective date of transfer with the accepting program. All data and records in UNet [SM] from the closing transplant program will transfer without modification to the accepting program. Accepting programs would need to consider placing the candidate into an inactive status if an evaluation at their program is needed but not completed.

The proposal's strength includes providing a structure that can be tailored to the unique circumstances of a program's long-term inactivation or closure. The closing program must still provide choice as currently required and obtain patient consent. It provides OPTN review as well as requires a signed agreement among the hospitals with specified responsibilities. The process also authorizes the OPTN to facilitate transfers in sudden closures.

Accepting hospitals will be required to submit and implement a post-transfer evaluation plan to the OPTN to describe expected dates and a process to manage the newly transferred patients. This is both a strength and weakness of the proposal. The strength is that this allows hospitals to develop plans tailored to their specific needs and situations. The weakness is that there are no uniform standards and timeliness of patient evaluations may vary. Currently no plan is required and some may view this as burdensome. The committee will follow these plans if this proposal is implemented.

Weaknesses of the proposal include that the accepting transplant program will assume responsibility immediately upon transfer to manage a potentially large number of new patients. The proposal, however, does require that closing and accepting programs agree upon a date of transfer. This will allow accepting programs to identify and increase staff resources needed to efficiently facilitate the transfer and evaluations prior to the agreed upon transfer date.

Supporting Evidence/Modeling:

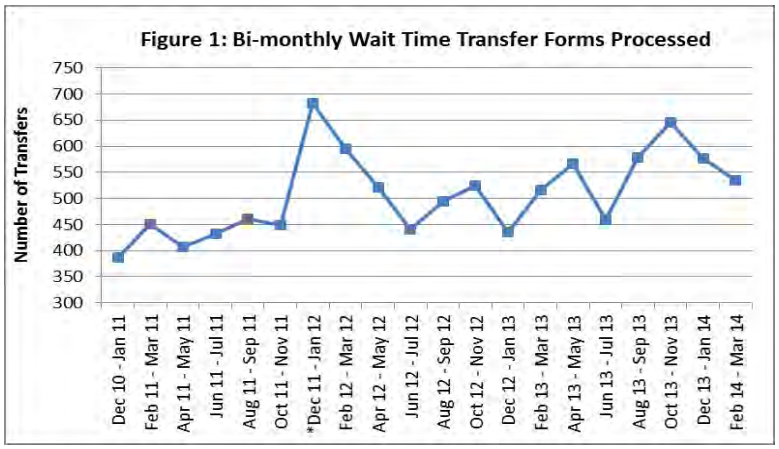
Transplant program closures can have a major impact on transplant prospects for patients listed with the closing program. In one instance, a hospital and all its transplant programs closed in December 2011 leaving over 400 candidates without access to services. Subsequently, another hospital started transplant services in early 2012 to serve the area which otherwise had no providers without requiring travel to the U.S. mainland. To restore and expedite their opportunity for transplant, a request was made to process these candidates as a group rather than individually. Consents were obtained and documented by the active transplant hospital. A list of these patients was provided to the OPTN. An information technology solution to transfer these patients collectively was employed substituting the new program's 8-character OPTN center code (e.g., ABCD-TX1) for the closed program. This effectively and efficiently transferred the entire candidate record, including waiting time. The OPTN Executive Committee approved waiving a second registration fee at the new program. This situation required special considerations and highlighted the need to address these types of circumstances in policy. The Committee's proposal would codify the authority and requirements to perform collective transfers.

Between January 2011 and December 31, 2013, 37 transplant hospitals withdrew designated OPTN program status (closed) for at least one program (45 total programs withdrawn). There were 1524 waitlisted candidates at these 45 programs within the 180 days prior to program closure. Over the three-year period from 2011-2013, this averaged to approximately 15 programs withdrawn from 12 transplant hospitals per year.

Individual transfers take approximately 30 minutes to process manually. The previously mentioned example would have required approximately 200 hours of OPTN staff time to process individually. It was estimated that an individual process for this situation would have taken one to two months to complete. The downside to this would have been taking needed resources away from routine transfers and potentially reducing transplant opportunities due to a slower and more inefficient process. By relying solely on signed individual forms, it might be possible that some patients would be missed or further delayed into being transferred to the new program.

Between December 2010 and March 2014, 10,158 individual Wait Time Transfer Forms were processed by the OPTN Contractor, averaging 254 individual forms per month (Figure 1). Transfers resulting from long-term inactivation or closures present an opportunity to overwhelm

Figure 1: Bi-monthly Wait Time Transfer Forms Processed



*Data Source: Organ Center, UNOS. *410 collectively transferred candidates not included.*

the system designed for individual transfers. Furthermore, the average transplant hospital in May 2014 had 496 total candidates. Nearly half (49%) of transplant hospitals have more than 300 candidates and 40 transplant hospitals have more than 1,000 candidates. Allowing use of an automated, collective transfer function would more efficiently transfer patients faced with a transplant program or hospital closure and minimize disruption to the Organ Center's current individual transfer process.

- **Expected Impact on Living Donors or Living Donation:**

Living donation candidates registered in UNet [SM] who indicate a willingness to accept deceased donor organs could be impacted. The impact could be a more efficient transfer to the receiving transplant hospital and ability to receive deceased donor organ offers.

- **Expected Impact on Specific Patient Populations:**

This proposal will not have a disproportionate impact on any specific patient population other than those populations who are patients at a closing or long-term inactivating transplant program.

- **Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

This proposal supports the following OPTN Strategic Plan Goals:

  - Promote transplant patient safety
  - Promote efficient management of the OPTN

The proposal promotes transplant patient safety, as all information will be transferred electronically reducing possibilities for data entry or transcription errors if records are re-entered or manually adjusted. The proposal promotes efficient management of the OPTN by converting an individual process to a collective process, reducing opportunity for lost paperwork and transfer processing time, and restoring opportunity for transplant in a timely manner.

- **Plan for Evaluating the Proposal:**

The primary goal of this proposal is to ensure that patients from closing transplant programs have the opportunity to transfer their care to active transplant programs in a timely manner.

In order to track the effectiveness of the proposed bylaw changes, the Committee will review data regarding the frequency of collective waitlist transfer requests, the number of patients collectively transferred, and the processing time for the collective transfers versus comparable time for individual transfers.

- **Expected Implementation Plan:**

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015. If passed, the proposal would go into effect September 1, 2015.

- **Communication and Education Plan:**
-

This proposal will affect only transplant hospitals and their patients for programs entering into long-term inactivity, withdrawal, or termination. The customary policy notice will be used for communicating changes to the community. UNOS staff will be available to answer individual questions.

-
- **Compliance Monitoring:**

The OPTN Contractor will review the written collective patient transfer agreement and plan for completeness and suitability. A written progress report from the accepting transplant program must be submitted to staff no later than 90 days from the actual patient transfer date. Noncompliance with submission of this report will result in referral to the Membership and Professional Standards Committee (MPSC). After receipt of the 90 day report staff will revisit the submitted plan to assess if it is accomplishing the desired safe and efficient evaluation of transferred patients. If a staff review of the plan finds concerns, then a referral can be made to the MPSC for its consideration regarding potential nonfulfillment with the original plan.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

3.6.C Individual Waiting Time Transfers

A candidate may transfer primary waiting time from one transplant hospital to another if it meets the requirements below:

1. The candidate must be registered at both transplant hospitals.
2. One of the transplant hospitals must submit a Wait Time Transfer Form to the OPTN Contractor.
3. The OPTN Contractor will transfer the primary qualifying date and waiting time accrued from the earlier transplant hospital to the new transplant hospital.
4. If the candidate chooses not to have multiple registrations, the OPTN Contractor will remove the candidate from the waiting list of the earlier transplant hospital.

If the candidate chooses to have multiple registrations, the OPTN Contractor will exchange the primary waiting time from the transplant hospital that had the primary qualifying date and waiting time with the more recent transplant hospital.

The OPTN Contractor will send a notice of the primary waiting time transfer to each of the transplant hospitals involved.

3.8 Collective Patient Transfers

The OPTN Contractor may collectively transfer patients from transplant programs with a status of long-term inactive, withdrawal, or termination, to one or more transplant programs according to *Appendix K: Transplant Program Inactivity, Withdrawal, and Termination* of the OPTN Bylaws. Candidates transferred as part of a collective transfer will retain waiting time according to *Appendix K.6: Transferred Candidates Waiting Time.*

3.~~8~~9 Removing Candidates from the Waiting List

OPTN Bylaws:

K.6 Transferred Candidates Waiting Time

To ensure equity in waiting times and ease the transfer of candidates from the waiting list, the candidates at programs that voluntarily inactivate, withdraw or lose designated transplant program status will:

1. Retain existing waiting time.
2. Continue to accrue waiting time according to their status on the waiting list at the time of the program's inactivation, withdrawal, or termination of designated transplant program status.

This total accrued waiting time can be transferred to the candidate's credit when the candidate is listed with a new transplant program.

The OPTN Contractor may collectively transfer patients from a transplant program, with a status of long-term inactive, withdrawal, or termination, to one or more active transplant programs.

The transferring transplant program must complete *all* of the following before a collective transfer:

1. All required patient notifications according to *Section K.3 Long-term Inactive Transplant Program Status* or *Section K.4 Withdrawal or Termination of Designated Transplant Program Status.*

2. A written agreement with each accepting transplant program that includes *all* of the following:
    a. Request for collective transfer of candidates' waiting times
    b. List of patient names and identifiers to be transferred
    c. Mutually agreed upon transfer date
    d. Assurance of notification and consent according to *Section K.5 Transition Plan during Long-term Inactivity, Termination, or Withdrawal*
    e. Acknowledgement that all patient information and records available to the OPTN Contractor will be transferred without modification
    f. Acknowledgement that the transplant program accepting the patients accepts responsibility for patient notification and management according to all applicable OPTN Policies and Bylaws

Each accepting transplant program must develop and implement a plan that includes *all* of the following:
1. Procedure for immediate review and designation of appropriate candidate waiting list status upon completion of the collective transfer
2. Expected date for completing full evaluations and subsequent waiting list status adjustments on collective transfer candidates according to the accepting programs' selection and listing protocol

Upon receipt of the written agreement and plan, the OPTN Contractor will review the information and provide an expected collective transfer completion date to all the transplant programs involved. After the collective transfer process has been completed, the OPTN Contractor will provide written notification to the transplant programs.

The accepting hospital must submit a progress report containing a status update on each collective transfer candidate to the OPTN Contractor within 90 days after the collective transfer is completed.

If the transferring transplant program no longer qualifies as a designated transplant program and does not complete the requirements according to *Appendix K*, the OPTN Contractor may approve and complete a collective transfer of candidates' registrations and waiting times if the accepting transplant program requests in writing to complete the transfer.

At-a-Glance

Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18

- **Affected/Proposed Policy:** 9.1 (Status and Score Assignments); 9.1.B (Pediatric Status 1A Requirements); 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older)

- **Pediatric Transplantation Committee**

  Most organ candidates automatically retain pediatric priority if they turn 18 while waiting for a transplant. Under current liver policy, if a candidate turns 18 years old while waiting in a MELD score (i.e., not Status 1A, Status 1B, or inactive status), the candidate does not automatically retain pediatric classification. Rather the registering transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list, but returns to the waiting list as an adult, the registering transplant program has the ability to apply to the RRB for a pediatric classification exception for this candidate. Both of these exception processes are inconsistent with allocation policy for most other organs. The RRBs have been consistent in their decision-making on these applications, making review of these applications unnecessary and easily automated. The Pediatric Transplantation Committee proposes the automatic transfer of pediatric classification for all candidates who turn 18 while waiting for a liver transplant. Further, the Pediatric Transplantation Committee seeks to eliminate the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18 but has since been removed and reregistered.

- **Affected Groups**
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Candidates

- **Number of Potential Candidates Affected**
  Since June 2013, the RRBs have reviewed and approved 12 pediatric classification exceptions. As of June 20, 2014, 38 liver candidates that would qualify for automatic pediatric classification under this proposal, but not under current policy, were actively waiting.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal seeks to increase pediatric access to transplant, fulfilling the charge of the Final Rule that the OPTN develop equitable allocation policy that especially considers the unique health care needs of children (Code of Federal Regulations, title 10, sec. 121.8[1]; 42 USC Sec. 274 (b)(2)(M)). This proposal also promotes the efficient management of the OPTN, which is a goal of the OPTN Strategic Plan.

[1] Code of Federal Regulations, Organ Procurement and Transplantation Network, title 42, sec. 121.8.

Proposal to Automatically Transfer Pediatric Classification for Registered Liver Candidates Turning 18

Affected/Proposed Policy: 9.1 (Status and Score Assignments); 9.1.B (Pediatric Status 1A Requirements); 9.1.C (Pediatric Status 1B); 9.3.A (Pediatric Status Exception for Candidates 18 Years or Older)

Pediatric Transplantation Committee

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

Most organ candidates automatically retain pediatric priority if they turn 18 while waiting for a transplant[2,3,4,5]. Under current liver policy, if a candidate turns 18 years old while waiting in a MELD score (i.e., not Status 1A, Status 1B, or inactive status), the candidate does not automatically retain pediatric classification. Rather the registering transplant program is responsible for requesting a pediatric classification exception from the Regional Review Board (RRB). Currently only Status 1A and Status 1B liver candidates turning 18 years old while waiting automatically retain pediatric classification. Additionally, if a candidate was ever registered as a pediatric patient and was subsequently removed from the waiting list, but returns to the waiting list as an adult, the registering transplant program has the ability to apply to the RRB for a pediatric classification exception for this candidate. Pediatric classification for an affected candidate operationally means prioritization as a 12 to 17 year old candidate on the liver match run. Both of these exception processes are inconsistent with allocation policy for most other organs. The RRBs have been consistent in their decision-making on these applications; candidates that turn 18 while waiting for liver transplant have been approved for pediatric classification, while adult candidates that were ever registered as pediatric candidates but have since been removed and reregistered were denied. The Pediatric Transplantation Committee believes that current policy historically has not been well-understood in the community. Requests to the RRBs have only recently become more frequent. Of the 15 exceptions that have been requested since May 24, 2004, 12 were requested after the OPTN published an informational article on June 13, 2013 regarding current policy. The Pediatric Transplantation Committee proposes that pediatric classification be automatically transferred for all candidates who turn 18 while waiting for a liver transplant. Further, the Pediatric Transplantation Committee seeks to eliminate the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18 but has since been removed and reregistered. These changes would make liver policy consistent with that of most other organs in regards to how candidates turning 18 while waiting are classified.

[2] Policy 6.1: Status Assignments, Organ Procurement and Transplantation (OPTN) Policies

[3] Policy 8.5.H: Allocation of Kidneys from Deceased Donors with KDPI Scores less than or equal to 20%, Organ Procurement and Transplantation (OPTN) Policies (pending implementation)

[4] Policy 8.5.I: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 20% but Less Than 35%, Organ Procurement and Transplantation (OPTN) Policies (pending implementation)

[5] Policy 11.4.A: Kidney-Pancreas Waiting Time Criteria for Candidates Less than 18 Years Old, Organ Procurement and Transplantation (OPTN) Policies (pending implementation)

Background and Significance of the Proposal:

In spring 2013, the Pediatric Transplantation Committee requested that staff publish an article explaining the pediatric classification exception process for liver candidates. Committee members did not believe that the current policy was well-understood in the community. This speculation was verified when 12 applications were submitted after the June 13, 2013 article was published, when only 3 had been requested in the previous 9 years.

In reviewing the exception applications, the Pediatric Transplantation Committee learned that the RRBs have been consistent in their decision-making; candidates that turn 18 while waiting for liver transplant have been approved for pediatric classification, while adult candidates that were ever registered as pediatric candidates but have since been removed and reregistered were denied. Pediatric Transplantation Committee members proposed the automatic transfer of pediatric classification for all candidates who turn 18 while waiting for a liver transplant. They also proposed eliminating the pediatric classification exception process for an adult candidate who was ever on the waiting list prior to age 18, but has since been removed and reregistered. These proposed changes would make liver policy consistent with that of most other organs in regards to how candidates in these specific situations are classified. They would also contribute to the fair and efficient management of the OPTN by eliminating two unnecessary exception processes.

The Pediatric Transplantation Committee sent the Liver and Intestinal Organ Transplantation Committee a memorandum on December 12, 2013, requesting its feedback on the proposed policy changes. On a February 14, 2014 conference call, the Liver and Intestinal Organ Transplantation Committee indicated their general support for the proposed changes with the suggestion that the Pediatric Transplantation Committee specify an age after which a candidate would no longer qualify for pediatric classification, also referred to as a cap. The Pediatric Transplantation Committee considered but ultimately decided against the Liver and Intestinal Organ Transplantation Committee's suggestion, since a cap is inconsistent with other organ allocation policies. Furthermore, Pediatric Transplantation Committee members could not propose an evidence-based cap due to the small number of pediatric liver candidates that turn 18 while waiting. The Pediatric Transplantation Committee affirmed that, as with any allocation policy, adequate and appropriate registration of patients and good waiting list management is always necessary.

The Pediatric Transplantation Committee voted to approve final policy language on July 9, 2014 (14 yes, 0 no, 0 abstentions). The Liver and Intestinal Organ Transplantation Committee considered this proposal on an August 6, 2014 conference call and unanimously voted to support it.

Supporting Evidence and/or Modeling:

The Pediatric Transplantation Committee reviewed a descriptive data analysis of candidates currently waiting that would qualify for automatic pediatric classification under this proposed policy. Thirty-eight candidates aged 18 or older, who had been registered prior to turning 18, were still waiting with a MELD score on June 20, 2014. Over 70% (27) of these candidates were 15 to 17 years old at registration. Registered at 22 different centers, the candidate age ranged from 18 to 33 years, though only 11% (4/38) were currently older than 25. Time spent on the waiting list ranged from less than 1 to 17 years. Most of the candidates had a MELD score less than 13. Five candidates had re-certifications that were past due, so they had been assigned a

MELD score of 6. None of the candidates had a previous liver transplant. Most had received at least one offer, and the most common refusal reason was donor age or quality. There was not a prevalent diagnosis among candidates. After careful consideration of the data, the Pediatric Transplantation Committee decided to proceed with the proposed policy. As with any allocation policy, adequate and appropriate registration of patients and good waiting list management is always necessary.

Expected Impact on Living Donors or Living Donation:

Not applicable

Expected Impact on Specific Patient Populations:

This proposal eliminates the need for transplant programs to petition the RRB on behalf of candidates turning 18 while waiting for a liver transplant in order to retain pediatric classification. In contrast to an automatic transfer of pediatric classification, an exception process is less efficient and the outcome of these applications is not guaranteed. Furthermore, evidence suggests that historically more candidates could have benefitted from a pediatric classification exception than applications were submitted, most likely because this policy is inconsistent with that of other organs and not well-understood.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal seeks to increase pediatric access to transplant, fulfilling the charge of the National Organ Transplant Act (NOTA) and the Final Rule that the OPTN develop equitable allocation policy that especially considers the unique health care needs of children (Code of Federal Regulations, title 10, sec. 121.8[6]; 42 USC Sec. 274 (b)(2)(M)). Eliminating the pediatric classification exception process for liver candidates also promotes the efficient management of the OPTN, which is a goal of the OPTN Strategic Plan. The RRBs have been consistent in their decision-making on these applications, making review of these applications unnecessary and easily automated.

Plan for Evaluating the Proposal:

The following data will be provided to the Pediatric Transplantation Committee after the policy has been in place for at least 6 months:

- The number of candidates who are still waiting in a MELD score after turning 18 but were registered prior to turning 18 by candidate age after policy implementation.
- The number of non-Status 1A and non-Status 1B deceased donor liver transplants by recipient age group at registration (0-11, 12-17, 18+) and donor age group (0-10, 11-17, 18+) before and after policy implementation.

The data will be provided on an annual basis for up to three years after policy implementation.

Additional Data Collection:

No additional data collection is required.

[6] Code of Federal Regulations, Organ Procurement and Transplantation Network, title 42, sec. 121.8.

Expected Implementation Plan:

This policy will be implemented upon Board approval using a manual solution. Programming in UNet[SM] will eventually be required to fully automate transfer of pediatric classification. This policy will not require any changes to the Liver Regional Review Board Operational Guidelines. No action is required of liver programs.

Communication and Education Plan:

The OPTN will follow established protocols to inform members of the Public Comment period and educate them on any policy changes through Policy Notices. Upon implementation, the OPTN will publish an article informing the community that transplant hospitals no longer have to petition the RRB for continued pediatric classification for candidates turning 18 while waiting for a liver transplant. Once programming is complete, UNOS will update UNet[SM] Help Documentation and distribute a System Notice to UNet[SM] users.

Compliance Monitoring:

This proposal will not affect monitoring of liver programs.

Policy or Bylaw Proposal:

9.1 Status and Score Assignments

Each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. Liver candidates can also be assigned a priority status if the candidate meets the requirements for that status.

Liver candidates at least 18 years old at the time of registration may be assigned *any* of the following:

- Adult status 1A
- ~~Inactive status~~
- Calculated MELD score
- Exception MELD score
- Inactive status
- ~~Pediatric status 1A or 1B with pediatric classification, if the candidate is registered on the waiting list when less than 18 years old and remains on the waiting list, or registers again after turning 18 years old or older and meets the requirements for that status.~~

Liver candidates less than 18 years old at the time of registration may be assigned *any* of the following:

- Pediatric status 1A
- Pediatric status 1B
- ~~Inactive status~~
- Calculated MELD or PELD score
- Exception MELD or PELD score
- Inactive status

Liver candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, will be classified as a 12 to 17 year old for the purposes of allocation in:

- *Policy 9.6.F: Allocation of Livers from Deceased Donors 11 to 17 Years Old*
- *Policy 9.6.G: Allocation of Livers from Deceased Donors Less than 11 Years Old*
- *Policy 9.6.J: Allocation of Liver-Intestines from Donors Less than 11 Years Old*

If the candidate is removed from the waiting list at any time and returns to the waiting list after turning 18 years old, the candidate must then be registered as an adult.

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of ~~initial~~ registration. This includes candidates ~~who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration~~ less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has at least *one* of the following conditions:

    a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease and has at least *one* of the following criteria:
        i. Is ventilator dependent
        ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iii. Has an international normalized ratio (INR) greater than 2.0

    b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
        i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
        ii. INR greater than or equal to 2.5
        iii. Total bilirubin greater than or equal to 10 mg/dL
        iv. Acidosis, defined as *one* of the following:
            - Arterial pH less than or equal to 7.30
            - Venous pH less than or equal to 7.25
            - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

    c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant

    d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of ~~initial~~ registration. This includes candidates ~~who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration~~ less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has *one* of the following conditions:

    a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.

    b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.

    c. Chronic liver disease with a MELD greater than 25 for adolescent candidates 12 to 17 years old, or a PELD greater than 25 for candidates less than 12 years old, and has at least *one* of the following criteria:
        i. Is on a mechanical ventilator
        ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
        iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

    d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
        i. Is on a mechanical ventilator
        ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
        iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.

~~9.3.A Pediatric Status Exception for Candidates 18 Years or Older~~

~~Liver candidates with a MELD score initially registered on the waiting list when less than 18 years old who remain on the waiting list or are registered again after turning 18 years old may be assigned the appropriate pediatric classification by exception. The transplant hospital must apply for the exception and include justification to the applicable RRB that the candidate is considered, by consensus medical judgment and using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having pediatric classification.~~

9.3.~~B~~A MELD/PELD Exception Applications

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

At-a-Glance

Policy Rewrite Parking Lot "Quick Fixes"

- **Affected/Proposed Policy:** Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.9 (Required Deceased Donor Infectious Testing), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.3.G.iii (Recommended Minimum Specifications for Dynamic Contrast-enhanced CT or MRI of the Liver), 9.3.G.iv (Imaging Requirements for Class 5 Lesions), 9.3.G.ix (Compliance Monitoring), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts)

- **Policy Oversight Committee (POC)**

  In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and, the rewritten Policies became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

  This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the rewrite parking lot and offers the corrected policy language to further clarify the OPTN Policies.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators

Transplant Physicians/Surgeons
Transplant Program Directors
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Compliance with OPTN Strategic Plan and Final Rule**
  By further clarifying these policies, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. Since it will also enhance understanding and compliance, the proposed improvements to policy language could increase patient safety.

- **Specific Requests for Comment**
  The Committee invites comment on whether the proposed language is more easily understood and whether these substantive changes are appropriate. In particular, the Committee request comment on the sections of policies 1.4, 2.5, 2.7, 9.3, and 20, where "should" was changed to "must" and therefore are now requirements rather than recommendations.

Policy Rewrite Parking Lot "Quick Fixes"

Affected/Proposed Policy: Policies 1 (Administrative Rules and Definitions), 2.5 (Hemodilution Assessment), 2.7.B (Informing Personnel), 2.9 (Required Deceased Donor Infectious Testing), 2.11.A (Required Information for Deceased Kidney Donors), 2.14 (Deceased Donor Management), 3.6.B.i (Non-function of a Transplanted Kidney), 3.8.B (Removing Pancreas Islets Candidates from the Waiting List), 5.3.A (Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)), 5.4.C (Liver Offers), 5.4.E (Backup Organ Offers), 8.2.B (Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings), 8.3 (Points), 9.1.A (Adult Status 1A Requirements), 9.1.B (Pediatric Status 1A Requirements), 9.1.C (Pediatric Status 1B), 9.1.D (MELD Score), 9.1.F (Liver-Intestine Candidates), 9.3.D (Specific MELD/PELD Exceptions), 9.3.F (Candidates with Cholangiocarcinoma), 9.3.G.iii (Recommended Minimum Specifications for Dynamic Contrast-enhanced CT or MRI of the Liver), 9.3.G.iv (Imaging Requirements for Class 5 Lesions), 9.3.G.ix (Compliance Monitoring), 9.5 (Points), 9.5.A (Points for Waiting Time), 9.6.H (Allocation of Liver-Intestines), 9.7.C (Rights Conferred by the Allocation System), 11.2 (Points), 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials), 15.1 (Patient Safety Contact), 15.2 (Potential Candidate Screening Requirements), 15.4.B (Requirements for Living Donor Recovery Hospital and Host OPOs), 16.2 (Organs Recovered by Living Donor Recovery Hospitals), 18.1 (Data Submission Requirements), 18.2 (Timely Collection of Data), 19.9 (Access to Recipient Outcomes Data), 20.2.A (Booking Travel), 20.4.B (Transportation To and From the Airport), 20.4.C (Rental Cars), 20.8.A (Expense Reimbursement Form), 20.8.B (Receipts)

Policy Oversight Committee (POC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and subsequently, the rewritten Policies became effective February 1, 2014[1]. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the parking lot and offers the corrected policy language to further clarify the OPTN Policies.

Background and Significance of the Proposal:
In 2013 the POC sponsored the OPTN Policies Plain Language Rewrite, which was passed by the Board and, the rewritten Policies became effective February 1, 2014. The plain language rewrite included plain language changes and reorganization only, and did not make any substantive changes to the Policies. As a result, during the rewrite, the many reviewers identified a number of issues that would require substantive changes to the Polices; these issues were recorded in the rewrite "parking lot" to be addressed in the future.

[1] See *OPTN Policies Plain Language Rewrite Policy Notice*

This proposal identifies the "quick fixes" or easy, non-controversial changes that are currently in the rewrite parking lot and offers the corrected policy language to further clarify the OPTN Policies.

- **Collaboration:** UNOS staff collaborated to identify the quick fixes and possible corrections to the Policies. Drafts of the parking lot proposed changes were circulated to all the OPTN/UNOS Committees and their comments and concerns were discussed and addressed by staff and the POC.
- **Alternatives considered:** The Committee explored the idea of waiting and addressing these issues as part of other projects the Committees are working on or to wait and address all the parking lot issues at one time. However, the POC recognized that these non-controversial quick fixes could be easily made and would clarify Policies for members so there was no benefit to waiting.

  Prior to the 2013 plain language rewrite, members frequently asked whether a policy was a requirement or a recommendation. The 2013 rewrite, therefore, attempted to distinguish between member requirements and recommendations. Policy language was standardized to use "must" for requirements and "should" for recommendations. These recommendations were left in the 2013 plain language rewrite with the intention to further clarify them at a later time, especially given that the goal of the plain language rewrite was to not make substantive changes to the policies. Options to address these recommendations included converting them into requirements (using "must" instead of "should") or clarifying the conditions when they are requirements (e.g., instead of writing that something *should* occur, write that it *must occur in certain situations*). This proposal has both of these solutions.

- **Strengths and weaknesses:** This proposal's strength is that it further clarifies the OPTN Policies. The proposal's weakness is that there are still outstanding issues that remain in the parking lot and will need to be assigned to the appropriate Committee to better address.

- **Description of intended and unintended consequences:** An intended consequence of the Committee is that these clarified policies will address issues identified by reviewers during the 2013 OPTN Policies plain language rewrite and further clarify Policies for members.

Supporting Evidence and/or Modeling:

The 2013 OPTN Policies Plain Language Rewrite identified issues with the current policies and highlighted the need to clarify language but many of those requested clarifications and changes would require substantive changes to the Policies that were not part of the scope of the Plain Language Rewrite. Some of these issues can now be addressed in this proposal as simple, non-controversial, substantive changes that will be approved as part of the typical policy development process, including public comment.

Specifically, the following changes were made:

- Changed "shoulds" to "must" where applicable and when the policy was able to be identified as a true requirement and not just a recommendation
- Standardized periods, including stating periods in days rather than weeks or months
- Streamlined the administrative rules and definitions, including the deletion of unnecessary or duplicative definitions.

- Made necessary changes to more consistently and appropriately use common terms in policies (for example, the use of transplant program versus transplant hospital or transplant center).
- Made simple, non-controversial changes to increase language clarity
- Made some headings more descriptive
- Clarified policy 9.1. (Status Scores and Assignments) by reorganizing lists
- Deleted 9.6.H (Allocation of Liver-Intestines) since it is a repeat of language in 9.1.F (Liver-Intestine Candidates)
- Deleted other outdated or superfluous sections including 9.7.C (Rights Conferred by the Allocation System) and 11.2 (Points)
- Made minor clerical and punctuation changes, including formatting

Expected Impact on Living Donors or Living Donation:

The proposed changes to policies 14.3 (Informed Consent Requirements), 14.3.A.ii (Living Kidney Donor Informed Consent Requirements), 14.7.B (Placement of Non-directed Living Donor Kidneys), and 14.8 (Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials) will improve members' understanding of the requirements for living donors and therefore may increase the safety of living donor transplants.

Expected Impact on Specific Patient Populations:
This proposed policy change will not directly impact any specific patient population.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

By further clarifying the OPTN Policies, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. This proposal also supports the specific strategy to improve readability of OPTN rules and requirements.

Plan for Evaluating the Proposal:

The Committee will continue communication with Regional Administration, Evaluation and Quality, and Membership to determine if members have questions or concerns about the new policy language.

Additional Data Collection:

There is no additional data collection required as a result of this policy change.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and, if approved, the clarified policies will become effective in September 2015.

Communication and Education Plan:

The following Communication & Education Activities will help notify members of the clarified policy language and will highlight the specific changes made to the policy language:

- Policy notice

- Presentation at Regional Meetings

Compliance Monitoring:
This proposal does not require any changes to the current compliance monitoring of these policy requirements.

Policy or Bylaw Proposal:

Policy 1: Administrative Rules and Definitions

1.1.A Time

A day ends at midnight Eastern Standard Time (EST).

~~1.1.B Gender~~

~~A word used in the masculine includes the feminine.~~

1.1.~~C~~B Headings, Notes, and History

~~The~~ All headings, ~~as well as the~~ notes, and history sections of these Policies, are intended only as guidance and to supplement the OPTN Policies and are not part of the Policies. These sections and headings are nonbinding to members and should not be treated as policy or used to infer the intent of the Policies.

1.1.~~D~~C Reporting of Information to the OPTN Contractor

Members must report requested information to the OPTN Contractor to fulfill membership requirements and to ensure compliance with OPTN Policies and Bylaws. The OPTN Contractor will determine the required method and format for reporting any information required by OPTN Policies and Bylaws, including the requirement to submit specific forms at defined times.

1.2 Definitions

H

Histocompatibility Laboratory
A histocompatibility laboratory is a member of the OPTN. A histocompatibility laboratory member is any histocompatibility laboratory that performs histocompatibility testing, including but not limited to, Human Leukocyte Antigen (HLA) typing, antibody screening, compatibility testing, or crossmatching, and serves at least one transplant hospital member or OPO. Histocompatibility laboratory members are either independent or hospital-based. See also Independent Histocompatibility Laboratory and Hospital-based Histocompatibility Laboratory definitions in the *OPTN Bylaws*.

M

Match run
A ~~procedure~~ process that filters and ranks waiting list candidates based on deceased or non-directed living donor and candidate medical compatibility and organ-specific allocation criteria. A match run is also used to generate a set of potential exchanges for a KPD donor and candidate.

R

Receiving transplant program
The transplant program that receives a deceased or living donor organ from an OPO, transplant hospital, or recovery hospital.

Recipient
A candidate that has received an organ transplant.

~~**Recipient transplant hospitals**~~
~~Transplant hospitals that perform living donor transplants.~~

Recovery hospital
A healthcare facility that recovers living donor organs.

Z

Zero antigen mismatch
A candidate is considered a zero antigen mismatch with a deceased or living donor if *all* of the following conditions are met:

1. At least one donor antigen is identified for each of the A, B, and DR loci
2. At least one candidate antigen is identified for each of the A, B, and DR loci
3. The donor has zero non-equivalent A, B, or DR antigens with the candidate's antigens
4. The donor and the candidate have compatible or permissible blood types

In cases where a candidate or donor has only one antigen identified at an HLA locus (A, B, or DR), the antigens are considered to be identical at that locus. A zero-antigen mismatch may also be referred to as a zero mismatch or 0-ABDR mismatch.

1.4.D Telecommunications Outage

If the OPTN Contractor and members cannot communicate through telephone, affected members:

1. ~~Should~~ Must contact the OPTN Contractor by e-mail to determine operating procedures and to obtain assistance.
2. ~~Should~~ Must continue to use the OPTN computer match program for organ allocation and distribution.
3. Must document and report to the OPTN Contractor any variations in allocation or distribution during the telecommunications problems.

1.4.E OPTN Computer Match Program Outages

If the OPTN Contractor and members cannot communicate by any method and the OPTN computer match program is either not accessible or not operational, affected OPOs:

1. ~~Should~~ Must refer to recent matches of similar blood type and body size for ranking local transplant candidates.
2. ~~Should~~ Must use local transplant program waiting lists to match the best organ with waiting transplant candidates.
3. Must document and report to the OPTN Contractor their process for allocation during the outage.

Policy 2: Deceased Donor Organ Procurement

2.5 Hemodilution Assessment

OPOs ~~should~~ must use qualified (non-hemodiluted) blood samples for deceased donor serological screening tests if available. If a qualified sample is not available for testing, a hemodiluted sample ~~should~~ may be used for deceased donor screening tests.

If serological testing occurs on a hemodiluted blood sample, the host OPO must treat the deceased donor as presenting an increased risk for disease transmission as specified in the U.S. Public Health Services (PHS) Guideline.

Prior to screening, the host OPO must assess all potential deceased donor blood samples that were obtained for serological screening tests for hemodilution using a U.S. Food and Drug Administration (FDA) approved hemodilution calculation. The host OPO must document in the deceased donor medical record a complete history of all blood products and intravenous fluid transfusions the deceased donor received since admission to the donor hospital.

Additionally, the host OPO must report *all* of the following to the accepting transplant programs when a hemodiluted specimen is used in deceased donor screening tests:

1. Any screening results from the hemodiluted specimens.
2. The tests completed on the hemodiluted specimens.
3. The hemodilution calculation used for the hemodiluted specimens, if requested.

2.7.B Informing Personnel

The host OPO ~~should~~ must only inform health-care personnel caring for potential deceased donors or deceased donors who test positive for HIV ~~only~~ when it is necessary for making medical decisions.

2.9.A Kidney

With each kidney offer, the host OPO should provide the ~~recipient transplant hospital~~ receiving transplant program with the following biopsy information for kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85%, and for all other kidneys at the request of the accepting surgeon:

1. Wedge biopsy with the sample measuring approximately 10 mm (length) by 5 mm (width) and 5 mm (depth)
2. A sample that captures a minimum of 25 glomeruli
3. A frozen or fixed section slide, or the biopsy material, may accompany the kidney

2.11.A Required Information for Deceased Kidney Donors

The host OPO must provide *all* the following additional information for all deceased donor kidney offers:

1. Date of admission for the current hospitalization
2. Donor name
3. Donor ID
4. Ethnicity
5. Relevant past medical or social history
6. Current history of abdominal injuries and operations
7. Current history of average blood pressure, hypotensive episodes, average urine output, and oliguria
8. Current medication and transfusion history
9. Anatomical description, including number of blood vessels, ureters, and approximate length of each
10. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53 and DQB antigens. The lab is encouraged to report splits for all loci as outlined in *Policy 4: Histocompatibility*.
11. Indications of sepsis
12. Injuries to or abnormalities of ~~the~~ blood vessels, ureters, or kidney
13. Assurance that final blood and urine cultures
14. Final urinalysis
15. Final blood urea nitrogen (BUN) and creatinine
16. Recovery blood pressure and urine output information
17. Recovery medications
18. Type of recovery procedure, flush solution and method, and flush storage solution
19. Warm ischemia time and organ flush characteristics

2.14 Deceased Donor Management

The host OPO must make reasonable efforts to manage the deceased donor by addressing *all* of the following:

1. Maintaining ~~adequate~~ blood pressure for perfusion of vital organs
2. Monitoring vital signs
3. Administering IV therapy or drugs, as required
4. Administering antibiotic therapy, as required
5. Administering and monitoring fluid intake and output

The OPO must document that these efforts were made and report the results to the receiving OPOs or transplant hospitals.

Policy 3: Candidate Registrations, Modifications, and Removals

3.6.B.i Non-function of a Transplanted Kidney

Immediate and permanent non-function of a transplanted kidney is defined as *either*:

- Kidney graft removal within the first 90 days of transplant documented by an operative report of the removal of the transplanted kidney.
- Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has measured creatinine clearance (CrCl) or calculated glomerular filtration rate (GFR) less than or equal to 20 mL/min ~~on the date that is~~ within 90 days after the candidate's kidney transplant.

Kidney waiting time will be reinstated when the OPTN Contractor receives a completed *Renal Waiting Time Reinstatement Form* and the supporting documentation required above. The Estimated Post Transplant Survival (EPTS) score will also be calculated without interruption. The OPTN Contractor will send a notice of waiting time reinstatement to the transplant hospital involved.

3.8.B Removing Pancreas Islets Candidates from the Waiting List

The transplant ~~center~~ hospital must remove the candidate from the waiting list within 24 hours of the candidate receiving each islet infusion.

Policy 5: Organ Offers, Acceptance, and Verification

5.3.A Reporting Unacceptable Antigens for Calculated Panel Reactive Antibody (CPRA)

In order to list an unacceptable antigen for a candidate on the waiting list, the transplant ~~hospital~~ program must do at least *one* of the following:

- Define the criteria for unacceptable antigens that are considered as contraindications for transplant. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, prior blood transfusion, and unexpected positive crossmatches.
- Base unacceptable antigens on laboratory detection of human leukocyte antigen (HLA) specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant ~~hospitals~~ programs may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

5.4.C Liver Offers

The host OPO must make the initial liver offer using only a match run that is less than eight hours old. The host OPO may only re-execute the match run for use in allocation sooner than eight hours if *either* occurs:

- A previously accepted liver is later refused because there is a change in ~~specific~~ medical information or infectious disease test results related to the deceased liver donor
- The deceased donor liver has not been allocated within two hours of procurement

~~Any re-execution of the match system for the same deceased donor for other reasons must be retrospectively reviewed by the Regional Review Board (RRB).~~

5.4.E Backup Organ Offers

OPOs may make backup offers for all organs. Transplant ~~hospitals~~ programs must treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ. If a transplant ~~hospital~~ program refuses to consider or does not respond to a backup offer, the offer will be considered refused.

If a transplant ~~hospital~~ program accepts a backup offer, it may later refuse to accept the organ based on medical or logistical criteria. Transplant programs~~hospitals~~ ~~should~~ must be promptly notified of any change in deceased donor status or organ availability.

Policy 8: Allocation of Kidneys

8.2.B Deceased Donor Kidneys with Discrepant Human Leukocyte Antigen (HLA) Typings

Allocation of deceased donor kidneys is based on the HLA typing identified by the donor histocompatibility laboratory. If the recipient HLA laboratory identifies a different HLA type for the deceased donor, the kidney may be allocated according to the original HLA typing, or the ~~recipient transplant hospital~~ receiving transplant program may reallocate the kidney locally, according to *Policy 8: Allocation of Kidneys*.

8.3 Kidney Allocation Points

Candidates receive points according to *Tables 8-1* and *8-2* below.

Table 8-1: Kidney Points

If the candidate is:	And the following allocation sequence is used:	Then the candidate receives this many points:
Registered for transplant and meets the qualifying criteria described in *Policy 8.4: Waiting Time*	8.5.H, 8.5.I, 8.5.J, or 8.5.K	1/365 points for each day since the qualifying criteria in *Policy 8.4: Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	8.5.H, 8.5.I, or 8.5.J	3 points

Aged 0-10 at time of match and donor has a KDPI score <35%	8.5.H, 8.5.I	1 point
A prior living donor	8.5.H, 8.5.I, or 8.5.J	4 points
Sensitized (CPRA at least 20%)	8.5.H, 8.5.I, or 8.5.J	*See Table 8-2: Points for CPRA*
A single HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	1 point
A zero HLA-DR mismatch with the donor*	8.5.H, 8.5.I, or 8.5.J	2 points

*Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus.

Table 8-2: Points for CPRA

If the candidate's CPRA score is:	Then the candidate receives this many points:
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

Policy 9: Allocation of Livers and Liver-Intestines

9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not registered as status 1A until this form is submitted.

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:

   a. Fulminant liver failure, without pre-existing liver disease and currently in the intensive care unit (ICU), defined as the onset of hepatic encephalopathy within ~~8 weeks~~ 56 days of the first signs or symptoms of liver disease, and has at least *one* of the following criteria:
      i. Is ventilator dependent
      ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
      iii. Has an international normalized ratio (INR) greater than 2.0

   b. Anhepatic

   c. ~~b.~~ Primary non-function of a transplanted whole liver within 7 days of transplant, with ~~evidenced by at least *one* of the following:~~
      ~~i. Anhepatic~~Aaspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
         - International normalized ratio (INR) greater than or equal to 2.5
         - Arterial pH less than or equal to 7.30
         - Venous pH less than or equal to 7.25
         - Lactate greater than or equal to 4 mmol/L

      All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

   d. ~~c.~~ Primary non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
      ~~i. Anhepatic~~
      i. INR greater than or equal to 2.5
      ii. Arterial pH less than or equal to 7.30
      iii. Venous pH less than or equal to 7.25
      iv. Lactate greater than or equal to 4 mmol/L

   e. ~~d.~~ Hepatic artery thrombosis (HAT) within 7-days of transplant, with ~~evidenced by *either* of the following:~~
      ~~i. Anhepatic~~
      ~~ii.~~ A~~a~~spartate aminotransferase (AST~~)~~ greater than or equal to 3,000 U/L and at least *one* of the following:
         - INR greater than or equal to 2.5
         - Arterial pH less than or equal to 7.30
         - Venous pH less than or equal to 7.25
         - Lactate greater than or equal to 4 mmol/L

      All laboratory results reported for ~~any~~ the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

      Candidates with HAT in a transplanted liver within 14 days of transplant not meeting the above criteria will be listed with a MELD of 40.

   f. ~~e.~~ Acute decompensated Wilson's disease

9.1.B Pediatric Status 1A Requirements

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list, or have returned to the waiting list after initial registration.
2. The candidate has at least *one* of the following conditions:

    a. Fulminant liver failure without pre-existing liver disease, defined as the onset of hepatic encephalopathy within ~~8 weeks~~ 56 days of the first signs and symptoms of liver disease and has at least *one* of the following criteria:
        i. Is ventilator dependent
        ii. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
        iii. Has an international normalized ratio (INR) greater than 2.0

    b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
        i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
        ii. INR greater than or equal to 2.5
        iii. Total bilirubin greater than or equal to 10 mg/dL
        iv. Acidosis, defined as *one* of the following:
            - Arterial pH less than or equal to 7.30
            - Venous pH less than or equal to 7.25
            - Lactate greater than or equal to 4 mmol/L

        All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

    c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant

    d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

To assign a candidate pediatric status 1B, the candidate's transplant hospital must submit a *Liver Status 1B Justification Form* to the OPTN Contractor. A candidate is not registered as status 1B until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of initial registration. This includes candidates who are currently 18 years old and greater but remain on the waiting list or have returned to the waiting list after initial registration.
2. The candidate has *one* of the following conditions:

a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.

b. The candidate has an organic acidemia or urea cycle defect and a MELD or PELD exception score of 30 points for at least 30 days.

c. Chronic liver disease with a calculated MELD greater than 25 for adolescent candidates 12 to 17 years old, or a calculated PELD greater than 25 for candidates less than 12 years old, and has at least *one* of the following criteria:
   i. Is on a mechanical ventilator
   ii. Has gastrointestinal bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours
   iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension

d. Chronic liver disease and is a combined liver-intestine candidate with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates* and has at least *one* of the following criteria:
   i. Is on a mechanical ventilator
   ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
   iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
   iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension

9.1.D MELD Score

Candidates who are at least 12 years old receive an initial MELD score equal to:

$$0.957 \times \text{Log}_e(\text{creatinine mg/dL}) + 0.378 \times \text{Log}_e(\text{bilirubin mg/dL}) + 1.120 \times \text{Log}_e(\text{INR}) + 0.643$$

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 4.0 mg/dL:

- Candidates with a creatinine value greater than 4.0 mg/dL
- Candidates who received two or more dialysis treatments within the prior ~~week~~ 7 days
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior ~~week~~ seven days

The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

For candidates with an initial MELD score greater than 11, ~~T~~the MELD score is then re-calculated as follows:

$$\text{MELD} = \text{MELD}_{(i)} + 1.32*(137-\text{Na}) - [0.033*\text{MELD}_{(i)}*(137-\text{Na})]$$

Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.

9.1.E PELD Score

Candidates who are less than 12 years old receive a PELD score equal to:

0.436 (Age (<1 YR.)) – 0.687 x Log_e (albumin g/dL) + 0.480 x Log_e (total bilirubin mg/dL) + 1.857 x Log_e (INR) +0.667 (Growth failure (<- 2 Std. Deviations present))

The PELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.

Scores for candidates registered for liver transplantation before the candidate's first birthday continue to include the value of 0.436 until the candidate is 24 months old.

Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.

A candidate has growth failure if the candidate is more than two standard deviations below the candidate's expected growth based on age and gender using the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.

9.1.F Liver-Intestine Candidates

Candidates awaiting a liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old will receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. The transplant hospital must ~~verify~~ document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that ~~an intestinal~~ the transplant ~~is required and took place~~ was completed.

9.3.D Specific MELD/PELD Exceptions

Candidates meeting the criteria in *Table 9-2: Specific Standardized MELD/PELD Exceptions* are eligible for MELD or PELD score exceptions that do not require evaluation by the full RRB. The transplant program must submit a request for a specific MELD or PELD score exception with a written narrative that supports the requested score. Additionally, a candidate may receive a higher MELD or PELD score if the RRB has an existing agreement for the diagnosis. These agreements must be renewed on an annual basis.

Table 9-2: Specific Standardized MELD/PELD Exceptions

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cholangiocarcinoma	The information required according to *Policy 9.3.F: Candidates with Cholangiocarcinoma.*	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Cystic Fibrosis	The candidate has signs of reduced pulmonary function with forced expiratory volume at one second (FEV_1) that falls below 40 percent.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Familial Amyloid Polyneuropathy (FAP)	*All* of the following: 1. Clear diagnosis of FAP. 2. Echocardiogram showing the candidate has an ejection fraction greater than 40 percent. 3. Ambulatory status. 4. Identification of transthyretin (TTR gene) mutation (Val30Met vs. non-Val30Met). 5. Biopsy- proven amyloid in the involved organ.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.
Hepatic Artery Thrombosis (HAT)	Candidate has HAT within 14 days of transplant but does not meet criteria for status 1A in Policy *9.1.A: Adult Status 1A Requirements*.	Will receive a MELD score of 40.
Hepatocellular Carcinoma (HCC)	The information required according to *Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)*.	*See Policy 9.3.G: Candidates with Hepatocellular Carcinoma (HCC)*.
Hepatopulmonary Syndrome (HPS)	*All* of the following: 1. Clinical evidence of portal hypertension. 2. Evidence of a shunt. 3. PaO_2 less than 60 mmHg on room air. 4. No significant clinical evidence of underlying primary pulmonary disease.	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months that the candidate's PaO_2 remains under 60 mmHg.
Metabolic Disease	The information required according to *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases.*	See *Policy 9.3.E: Pediatric Liver Candidates with Metabolic Diseases.*

If the candidate has:	And submits to the OPTN Contractor evidence that includes:	Then the candidate:
Portopulmonary Hypertension	The candidate has a mean pulmonary arterial pressure (MPAP) below 35 mmHg following intervention. The diagnosis ~~should~~ must also include *all* of the following: 1. Initial mean pulmonary arterial pressure (MPAP) level. 2. Initial pulmonary vascular resistance (PVR) level. 3. Initial transpulmonary gradient to correct for volume overload. 4. Documentation of treatment. 5. Post-treatment MPAP less than 35 mmHg. 6. Post treatment PVR less than 400 dynes/sec/cm^{-5}..	Will receive a MELD score of 22 or PELD score of 28; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months if a repeat heart catheterization confirms that the mean pulmonary arterial pressure (MPAP) remains below 35 mmHg.
Primary Hyperoxaluria	The candidate has *all* of the following: 1. Is registered for a combined liver-kidney transplant. 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis. 3. Glomerular filtration rate (GFR) less than or equal to 25 mL/min, by six variable Modification of Diet in Renal Disease formula (MDRD6) or direct measurement of iothalamate or iohexol, for ~~six weeks~~ 42 or more days.	Will receive a MELD score of 28 or PELD score of 41; then will receive a MELD or PELD score equivalent to a 10 percentage point increase in the risk of three-month mortality every three months.

9.3. F Candidates with Cholangiocarcinoma

A candidate will receive the MELD/PELD exception in *Table 9-2: Specific MELD/PELD Exceptions* for cholangiocarcinoma, if the candidate's transplant hospital meets *all* the following qualifications:

1. Submit a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that ~~should~~ must include *all* of the following:
   a. Candidate selection criteria
   b. Administration of neoadjuvant therapy before transplantation
   c. Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
   d. Any data requested by the Liver and Intestinal Organ Transplantation Committee

2. Document that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and *one* of the following:
   a. Biopsy or cytology results demonstrating malignancy

b. Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
c. Aneuploidy

The tumor ~~should~~ must be considered un-resectable because of technical considerations or underlying liver disease.

3. If cross-sectional imaging studies demonstrate a mass, the mass ~~should~~ must be less than three cm.
4. Intrahepatic and extrahepatic metastases ~~should~~ must be excluded by cross-sectional imaging studies of the chest and abdomen at the time of the initial application for the MELD/PELD exception and every three months before the MELD/PELD score increases.
5. Regional hepatic lymph node involvement and peritoneal metastases ~~should~~ must be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) ~~should~~ must be avoided because of the high risk of tumor seeding associated with these procedures.

9.3.G Candidates with Hepatocellular Carcinoma (HCC)

9.3.G.iii ~~Recommended~~ Minimum Specifications for Dynamic Contrast-enhanced CT or MRI of the Liver

CT scans and MRIs performed for a Hepatocellular Carcinoma (HCC) MELD or PELD score exception application ~~should~~ must meet the criteria in *Table 9-3* and *Table 9-4* and must be interpreted by a radiologist at a transplant hospital. If the scan is inadequate or incomplete then the lesion will be classified as OPTN Class 0 and imaging must be repeated or completed to receive an HCC MELD/PELD exception.

Table 9-3: ~~Recommendations~~ Requirements for Dynamic Contrast-enhanced CT of the Liver

Feature:	CT scans ~~should~~ must meet the below specifications:
Scanner type	Multidetector row scanner.
Detector type	Minimum of 8 detector rows and must be able to image the entire liver during brief late arterial phase time window.
Slice thickness	M~~inimum~~aximum of 5 mm reconstructed slice thickness~~;~~. T~~t~~hinner slices are preferable especially if multi-planar reconstructions are performed.
Injector	Power injector, preferably dual chamber injector with saline flush and bolus tracking recommended.
Contrast injection rate	3 mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5 mL/kg body weight.
Mandatory dynamic phases on contrast-enhanced MDCT	1. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. 2. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. 3. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast.
Dynamic phases (Timing)	Use the bolus tracking or timing bolus.

Table 9-4: ~~Recommendations~~ Requirements for Dynamic Contrast-enhanced MRI of the Liver

Feature	MRIs ~~should~~ must meet the below specifications:
Scanner type	1.5T Tesla or greater main magnetic field strength. Low field magnets are not suitable.
Coil type	Phased array multichannel torso coil, unless patient-related factors precludes its use.
Minimum sequences	Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without fat saturation), T1-weighted in and out of phase imaging.
Injector	Dual chamber power injector with bolus tracking recommended.
Contrast injection rate	2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion, preferably resulting in vendor-recommended total dose.
Mandatory dynamic phases on contrast-enhanced MRI	1. Pre-contrast T1W: do not change scan parameters for post contrast imaging. 2. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. 3. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. 4. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast.
Dynamic phases (Timing)	The use of the bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal vein phase images ~~should~~ must be acquired 35 to 55 seconds after initiation of late arterial phase. Delayed phase images ~~should~~ must be acquired 120 to 180 seconds after the initial contrast injection.
Slice thickness	5 mm or less for dynamic series, 8 mm or less for other imaging.
Breath-holding	Maximum length of series requiring breath-holding ~~should~~ must be about 20-seconds with a minimum matrix of 128 x 256. Technologists must understand the importance of patient instruction about breathholding before and during scan.

9.3.G.iv Imaging Requirements for Class 5 Lesions

Nodules found on images of cirrhotic livers are classified according to *Table 9-5*. Use the largest dimension of each tumor to report the size of Hepatocellular Carcinoma (HCC) lesions. Nodules less than 1 cm are indeterminate and cannot be considered for additional priority.

Table 9-5: Classification System for Nodules Seen on Imaging of Cirrhotic Livers

Class	Description
0	Incomplete or technically inadequate study
5A	Must meet *all* of the following: 1. Single nodule ≥ 1 cm and < 2 cm. The maximum diameter of lesions ~~should~~ must be measured on late arterial or portal phase images.

Class	Description
	2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). 3. Washout during the later contrast phases and peripheral rim enhancement (capsule/pseudocapsule) on delayed phase *or* a biopsy. (A pre-listing biopsy is not mandatory.)
5A-g (growth)	Must meet *all* of the following: 1. Single nodule ≥ 1 cm and < 2 cm. The maximum diameter of lesions ~~should~~ must be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma). 3. Growth (maximum diameter increase) by 50% or more documented on serial MRI or CT obtained ≤ 6 months apart. Growth criteria do not apply to ablated lesions.
5B	Must meet *all* of the following: 1. Single nodule diameter ≥ 2 cm. and ≤ 5 cm. The maximum diameter of lesions ~~should~~ must be measured on late arterial or portal phase images. 2. Increased contrast enhancement on late hepatic arterial images (relative to hepatic parenchyma). 3. *One* of the following: a. Washout on portal venous/delayed phase. b. Late capsule or pseudocapsule enhancement. c. Growth (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained ≤ 6 month apart. Serial imaging and measurements ~~should~~ must be performed on corresponding contrast phases with the same modality preferred. Growth criteria do not apply to previously ablated lesions. d. Biopsy. (A pre-listing biopsy is not mandatory.)
5T (Treated)	Any OPTN Class 5 or biopsy-proven HCC lesion that was automatically approved upon initial application or extension and has subsequently undergone loco-regional treatment. OPTN Class 5T nodules qualify for continued priority points based on the pre-treatment classification of the nodules and are defined as: Past loco-regional treatment for HCC (OPTN Class 5 lesion or biopsy proven prior to ablation). Evidence of persistent/recurrent HCC such as, but not limited to, nodular or crescentic extra-zonal or intra-zonal enhancing tissue on late arterial imaging (relative to hepatic parenchyma) may be present.
5X	Lesions that meet radiologic criteria for HCC but are outside stage T2 as defined above will be considered Class 5X and are not eligible for automatic exception points.

9.3.G.ix Compliance Monitoring

The transplant hospital must maintain documentation of the radiologic characteristics of each OPTN Class 5 nodule. If growth criteria are used to classify a nodule as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging and measurements of the nodule.

For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN Contractor within 60 days of transplant. If the pathology report does not show evidence of HCC, the transplant hospital must also submit documentation or imaging studies confirming HCC at the time of assignment. The Liver and Intestinal Organ Transplantation Committee will review a transplant hospital when more than 10 percent of the HCC cases in ~~a~~ one-year ~~period~~ are not supported by the required pathologic confirmation or submission of clinical information.

9.5 Liver Allocation Points

Points are used for sorting liver candidates according to *Policy 9.6.D: Sorting Within Each Classification*.

9.5.A Points for Waiting Time

Points are assigned so that the status 1A or 1B candidate with the longest waiting time receives the most points as follows:

- 10 points for the candidate with the greatest total status 1A or status 1B ~~W~~waiting ~~T~~time within each classification
- A fraction of 10 points divided up among the remaining status 1A or status 1B candidates within each classification, based on the potential recipient's total waiting time

~~**9.6.H Allocation of Liver-Intestines**~~

~~Adult candidates awaiting a combined liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. Candidates less than 18 years old will receive 23 additional points to their calculated MELD/PELD score instead of the 10% increase. The transplant hospital must verify that an intestinal transplant is required and took place.~~

~~**9.7.C Rights Conferred by the Allocation System**~~

~~No individual or property rights are conferred by the liver allocation system.~~

Policy 11: Allocation of Pancreas, Kidney-Pancreas, and Islets

~~11.2 Points~~

~~No allocation priority is assigned to pancreas, kidney-pancreas, or islet candidates based on points.~~

Policy 14: Living Donation

14.3 Informed Consent Requirements

~~Education is important so that the potential living donor understands all aspects of the donation process, especially the risks and benefits.~~

14.3.A.ii Living Kidney Donor Informed Consent Requirements

The kidney recovery hospital must obtain informed consent from any potential living kidney donor that ~~must~~ includes written assurance by the potential living donor of *all* of the following:

1. That the potential donor is willing to donate.
2. That the potential donor is free from inducement and coercion.
3. That the potential donor has been informed that the potential living donor may decline to donate at any time.

The potential living donors must be offered an opportunity to stop the donor consent or evaluation process and to do so in a way that is protected and confidential. The ILDA must be available to assist the potential living donor during this process, according to *Policy 14.2*.

The kidney recovery hospital must document in the potential donor's medical record that the hospital provided the potential donor with *all* of the following:

1. Instruction about all phases of the living donation process, including consent, medical, and psychosocial evaluations, pre- and post-operative care, and required post-operative follow up according to *Policy 18.5: Living Donor*. Teaching or instructional material may include any media, or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the potential living donor is able to engage in a meaningful dialogue with the transplant program recovery hospital's staff.
2. The disclosure that the recovery hospital will take all reasonable precautions to maintain confidentiality for the potential living donor and recipient.
3. The disclosure that it is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value, including, but not limited, to cash, property, and vacations.
4. Disclosure that the recovery hospitals must provide an ILDA.
5. The transplant recipient outcome and transplanted kidney survival data according to *Table 14-1* that follows:

Table 14-1: Required Recipient Outcome and Transplanted Kidney Survival Data

If the recovery hospital and the recipient hospital:	Then:	Including *all* the following information:
Are the same	The recovery hospital must provide the potential living donor with both national and that hospital's program-specific transplant recipient outcomes from the most recent Scientific Registry of Transplant Recipients (SRTR) program~~hospital~~ specific reports.	1. National 1-year patient and transplanted kidney survival 2. The hospital's 1-year patient and transplanted kidney survival 3. Notification about all Centers for Medicare and Medicaid Services (CMS) outcome requirements not being met by the transplant hospital

If the recovery hospital and the recipient hospital:	Then:	Including *all* the following information:
Will not be the same and the recipient hospital is known	The recovery hospital must provide the potential living donor with both national and the recipient hospital's program-specific transplant recipient outcomes from the most recent SRTR program~~hospital~~-specific reports.	4. National 1-year patient and transplanted kidney survival 5. The recipient hospital's 1-year patient and transplanted kidney survival 6. Notification about all CMS outcome requirements not being met by the recipient hospital

6. Education about expected post-donation kidney function, and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the living donor in the future, to include:

    a. On average, living donors may have a 25-35% permanent loss of kidney function after donation.
    b. Baseline risk of ESRD for living kidney donors does not exceed that of the general population with the same demographic profile.
    c. Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60. The medical evaluation of a young potential living donor cannot predict lifetime risk of CKD or ESRD.
    d. Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney. The development of CKD and subsequent progression to ESRD may be faster with only one kidney.
    e. Dialysis is required if the donor develops ESRD.
    Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to *Policy 8.4.F: Prior Living Organ Donor.*
7. The disclosure of alternate procedures or courses of treatment for the recipient, including deceased donor transplantation, and that:

    a. A deceased donor kidney might become available for the recipient before the recovery hospital completes the potential living donor's evaluation or the living donor transplant occurs.
    b. Any transplant candidate might have risk factors for increased morbidity or mortality that are not disclosed to the potential living donor.

8. The disclosure that the potential living donor will receive a thorough medical and psychosocial evaluation.

9. The disclosure that health information obtained during the potential living donor's evaluation will be subject to the same regulations as all medical records and could reveal conditions that the transplant hospital must report to local, state, or federal public health authorities.

10. The disclosure that recovery hospitals are required to:

a. Report living donor follow up information, at the time intervals specified in *Policy 18.5: Living Donor*.
b. Have the potential living donor commit to post-operative follow up testing coordinated by the living donor recovery hospital.

11. The disclosure that any infectious disease or malignancy pertinent to acute recipient care discovered during the potential living donor's first two years of post-operative follow up care:

    a. Will be disclosed to the living donor
    b. May need to be reported to local, state or federal public health authorities
    c. Will be disclosed to the recipient's transplant hospital
    d. Will be reported to the OPTN Improving Patient Safety Portal.

14.7.B Placement of Non-directed Living Donor Kidneys

Prior to determining the placement of a non-directed living donor kidney, the recovery hospital must obtain the match run of its waiting list candidates from its local OPO or the Organ Center. When a non-directed living donor kidney is allocated, the recovery hospital must document how the organ is allocated and the rationale for allocation.

This requirement does not apply to non-directed living kidney donors who donate a kidney through ~~consent to participate in~~ a Kidney Paired Donation (KPD) arrangement.

14.8 Packaging, Labeling, and Transporting of Living Donor Organs, Vessels, and Tissue Typing Materials

Recovery hospitals are responsible for packaging and labeling any living donor organs, tissue typing specimens, or vessels that are recovered from living donors according to *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage* when *either* of the following occurs:

- Living donor organs, tissue typing specimens, or vessels are recovered and must be transported outside the recovery hospital
- A living donor organ, tissue typing specimens, or vessels require~~s~~ repackaging by a transplant hospital for transport outside the transplant hospital

Policy 15: Identification of Transmissible Diseases

15.1 Patient Safety Contact

Each OPO and transplant program must identify a patient safety contact and develop and comply with a written protocol for the patient safety contact to fulfill all the following responsibilities:

1. Be available 24 hours a day.
2. Receive notifications of potential disease transmission and related communication from the OPTN Contractor.
3. Receive relevant medical information that may affect or change recipient care.
4. Communicate any information regarding potential disease transmissions to the medical staff responsible for the recipient's clinical care at the transplant program as soon as possible, but no later than 24 hours after becoming aware of the potential disease transmission.
5. Facilitate communication about the current clinical status of any recipient when the transplant program is notified of a potential or proven disease transmission that may affect the recipient.

~~Transplant programs and OPOs must make this information available to the OPTN Contractor on request.~~

15.2 Potential Candidate Screening Requirements

To be eligible for an organ transplant, potential transplant candidates must be tested for human immunodeficiency virus (HIV), hepatitis B, and hepatitis C, unless the testing would violate state or federal laws. Potential candidates who test positive for HIV, hepatitis B, or hepatitis C ~~should~~ must be offered appropriate counseling.

The OPTN permits HIV test positive individuals as organ candidates if permitted by the transplant hospital. Care of HIV test positive organ candidates and recipients ~~should~~ must not deviate from general medical practice.

15.4.B Requirements for Living Donor Recovery Hospital and Host OPOs

The living donor recovery hospital or host OPO is responsible for *all* the following:

1. Communication of the suspected donor's and affected recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible, but no more than 24 hours after receipt, to any transplant programs, patient safety contacts, and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after recovery. The living donor recovery hospital or host OPO must document that this information is shared with all receiving transplant programs ~~recipient transplant hospitals~~ and tissue banks.

2. Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, but no later than 24 hours after receipt of test results or diagnosis.

3. Potential disease transmission follow up communication as follows, including:

    a. For deceased donors, completion and submission of the *Potential Disease Transmission Report Form* no later than 24 hours after reporting the event through the OPTN Improving Patient Safety Portal. This must include:
    i. The specific ~~recipient~~ receiving transplant program patient safety contact and tissue bank staff that were notified of the potential transmission
    ii. Disposition of all organs, tissues, and vessels
    iii. Any preliminary information available regarding any remaining deceased donor samples for additional testing, notification to state or local health department as appropriate for nationally notifiable infectious diseases, and whether an autopsy was performed on the deceased donor.

4. A follow up review of the event, in partnership with OPTN patient safety staff, to determine whether the deceased or living donor was diagnosed with a potentially transmissible disease or condition.

For all living and deceased donors, the Ad Hoc Disease Transmission Advisory Committee may request submission of a *Potential Disease Transmission Donor Follow-Up Report* 45 days after the initial reporting date. Patient safety staff may request additional information related to the living donor beyond 45 days, including pending test results, depending on the potentially transmitted disease or condition.

If a host OPO learns new information regarding a deceased donor as part of its required ~~living~~ donor follow up that indicates risk of potential transmission of disease or malignancy, the host OPO must report the information through the OPTN Improving Patient Safety Portal.

If a recovery hospital learns new information about a living donor during the first two years post donation that indicates risk of potential transmission of disease or malignancy, then the recovery hospital must do *at least* ~~*all of*~~ the following:

1. Disclose to the living donor that a potential disease transmission or malignancy must be reported to the ~~recipient transplant hospital~~ receiving transplant program and the OPTN Improving Patient Safety Portal
2. Notify the ~~recipient transplant hospital~~ receiving transplant program
3. Report the potential transmission through the OPTN Improving Patient Safety Portal

The recovery hospital may also need to report the new information to local, state, or federal public health authorities.

Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage

16.2 Organs Recovered by Living Donor Recovery Hospitals

Living donor recovery hospitals must follow all of the requirements for packaging, labeling, and transporting organs, tissue typing material, and vessels according to this Policy, with these differences:

1. While OPOs are responsible for packaging, labeling, and transporting deceased donor organs, vessels, and tissue typing samples, recovery hospitals are responsible for packaging, labeling, and transporting living donor organs, vessels, and tissue typing samples.
2. When a member repackages a living donor organ, they are not required to notify the member that originally packaged the organ.
3. Instead of the list of documents in *Policy 16.5: Documentation Accompanying the Organ or Vessel*, living donor organs must contain the blood type source documents, donor informed consent form, and the complete medical record of the living donor. Vessels that are shipped separately from living donor organs must include the same documents as are required for shipping living donor organs.
4. Blood samples and tissue typing materials must contain the donor ID and *one* of the following three identifiers: donor date of birth, donor initials, or a locally assigned unique ID. Each sample ~~should~~ must contain the donor's blood type and subtype, the type of tissue, and the date and time when the sample was obtained. The recovery hospital must document in the donor record all unique identifiers used to label blood samples and tissue typing materials.
5. The recovery hospital will provide specimens for tissue typing if requested. The minimum typing materials for living donor kidneys are~~:~~ two ACD (yellow top) tubes per kidney.

Policy 18 Data Submission Requirements

18.1 Data Submission Requirements

OPOs must provide donor information required for organ placement to the OPTN Contractor in an electronic data format as defined and required by the computer system. Deceased donor information required for organ placement must be submitted prior to organ allocation.

Members must report data to the OPTN using standardized forms. *Table 18-1* shows the member responsible for submitting each data form and when the ~~M~~member must submit the following materials to the OPTN Contractor.

This policy does not apply to VCA-only donors or VCA information for donors and recipients; however, for VCA-only procurements, Host OPOs must submit to the OPTN Contractor the Deceased donor registration (DDR) within 30 days after the procurement date.

Table 18-1: Data Submission Requirements

The following member:	*Must submit the following materials to the OPTN Contractor:*	*Within:*	*For the following groups:*
Histocompatibility Laboratory	*Donor histocompatibility* (DHS)	30 days after the OPO submits the deceased donor registration	For each donor typed by the laboratory
Histocompatibility Laboratory	*Recipient histocompatibility* (RHS)	*Either* of the following: • 30 days after the transplant hospital removes the candidate from the waiting list because of transplant • 30 days after the transplant hospital submits the *recipient feedback*	For each transplant recipient typed by the laboratory
OPOs, all	*Death notification records* (DNR)	30 days after the end of the month in which a donor hospital reports a death to the OPO or the OPO identifies the death through a death record review	For all imminent neurological deaths and eligible deaths in its DSA
OPOs, all	*Monthly Donation Data Report: Reported Deaths*	30 days after the end of the month in which a donor hospital reports a death to the OPO	For all deaths reported by a hospital to the OPO
Allocating OPO	*Potential transplant recipient* (PTR)	30 days after the match run date by the OPO or the OPTN Contractor	For each deceased donor organ that is offered to a potential recipient
Host OPO	*Deceased donor feedback*	7 days after the procurement date	

The following member:	*Must submit the following materials to the OPTN Contractor:*	*Within:*	*For the following groups:*
Host OPO	*Deceased donor registration* (DDR)	30 days after the *deceased donor feedback* form is submitted and disposition is reported for all organs	For all deceased donors and authorized but not recovered potential deceased donors
Recovery Hospitals	*Living donor feedback*	The time prior to donation surgery	For each potential living donor organ recovered at the hospital
Recovery Hospitals	*Living donor registration* (LDR)	60 days after the Recovery Hospital submits the *living donor feedback* form	For each living donor organ recovered at the hospital
Recovery Hospitals	*Living donor follow-up* (LDF)	60 days after the six-month, 1-year, and 2-year anniversary of the donation date	For each living donor organ recovered at the hospital
Transplant hospitals	*Organ specific transplant recipient follow-up* (TRF)	*Either* of the following: • 30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure • 14 days from notification of the recipient's death or graft failure	For each recipient followed by the hospital
Transplant hospitals	*Organ specific transplant recipient registration* (TRR)	60 days after transplant hospital submits the *recipient feedback* form	For each recipient transplanted by the hospital
Transplant hospitals	*Liver Post-Transplant Explant Pathology*	60 days after transplant hospital submits the *recipient feedback* form	For each liver recipient transplanted by the hospital
Transplant hospitals	*Recipient feedback*	24 hours after the transplant	For each recipient transplanted by the hospital

The following member:	*Must submit the following materials to the OPTN Contractor:*	*Within:*	*For the following groups:*
Transplant hospitals	*Recipient malignancy* (PTM)	30 days after the transplant hospital reports the malignancy on the *transplant recipient follow-up* form	For each recipient, with a reported malignancy, that is followed by the hospital
Transplant hospitals	*Transplant candidate registration* (TCR)	30 days after the transplant hospital registers the candidate on the waiting list	For each candidate on the waiting list or recipient transplanted by the hospital

18.2 Timely Collection of Data

Members must collect and submit timely information to the OPTN Contractor. Timely data on recipients and living donors is based on recipient or living donor status at a time as close as possible to the specified transplant event anniversary. *Table 18-2: Timely Data Collection* sets standards for when the member must collect the data from the patient.

This policy does not apply to VCA transplants.

Table 18-2: Timely Data Collection

Information is timely if this Member:	Collects this information for this form:	Within this time period:
Transplant hospital	*Organ specific transplant recipient registration* (TRR)	When the transplant recipient is discharged from the hospital or ~~six-weeks~~ 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor registration* (LDR)	When the living donor is discharged from the hospital or ~~six-weeks~~ 42 days following the transplant date, whichever is first
Recovery hospital	*Living donor follow-up* (LDF)	60 days before or after the six-month, 1-year, and 2-year anniversary of the donation date

Policy 19: Data Release
19.9 Access to Recipient Outcomes Data

OPOs may receive recipient outcomes data, without permission from the transplant hospital, for each deceased donor organ transplanted. This information would be used in determining the appropriateness of deceased donor selection and management techniques as well as quality assurance of the procurement process. The data would be accessed and downloaded through the OPTN Contractor. The members that receive the data will not publish or publicly disseminate outcomes of specific recipients, physicians, or institutions. These data fields are located on the *Transplant Recipient Registration* forms and include all of the following:

Recipient status (all organs)
- Living – date of hospital report
- Dead – date and cause of death
- Re-transplanted prior to hospital discharge – date
- Cause of retransplant (thoracic only)

Clinical information at discharge (kidneys only)
- Most recent serum creatinine prior to discharge
- Did kidney produce >40 mL of urine in first 24 hours?
- Did recipient need dialysis within first ~~week~~ 7 days?
- Did creatinine decline by 25% or more in first 24 hours on two separate serum samples taken within first 24 hours?

Transplanted kidney, liver, or pancreas status at discharge
- Functioning or failed
- If failed, date and cause
- Preservation Information (all organs)

Policy 20: Travel Expense and Reimbursement
20.2 Airfare and Rail Reimbursement

20.2.A Booking Travel

OPTN Contractor staff and members must use the approved OPTN Contractor travel agency to arrange all OPTN Contractor related travel and obtain a low-cost coach fare that will accommodate the traveler's needs. If the traveler chooses not to accept those flight arrangements, the OPTN Contractor will reimburse only up to the amount the approved OPTN travel agency would have paid.

~~Travelers should book airline reservations at least one month in advance of travel.~~

20.4.B Transportation To and From the Airport

The OPTN Contractor will reimburse *all* of the following costs:

1. Transportation between the airport and the traveler's home.
2. Transportation between the airport and the meeting location.
3. Parking fees at the airport from which the traveler departs.

Travelers ~~should~~ must use the least expensive, convenient option to travel to and from airports. The OPTN Contractor will not reimburse limousines unless the cost is shared with another

traveler and the total cost to the OPTN Contractor is no more expensive than cab fare.

20.4.C Rental Cars

The OPTN Contractor will not reimburse rental cars if less expensive modes of travel are available. The traveler must elect rental car insurance coverage and ~~should~~ must minimize additional rental car fees. If the traveler elects to rent a car when less expensive modes of travel are available, the OPTN Contractor will reimburse up to the amount of the estimated cab fare needed for the duration of the stay.

20.4.D Provided Ground Transportation

The OPTN Contractor will not reimburse the cost of any other ground transportation if the OPTN Contractor provides ground transportation between an airport and a meeting site and the person traveling could reasonably take advantage of this transportation.

20.8 Filing Expense Reports

20.8.A Expense Reimbursement Form

To request reimbursement from the OPTN Contractor, the traveler must complete and submit an OPTN Contractor expense reimbursement form with original receipts. Off-site OPTN members may submit scanned copies of the original receipts. The traveler must sign the expense reimbursement form and must include *all* of the following information:

1. Dates of travel
2. Reason for travel
3. Meeting location and name of event
4. To whom the reimbursement check will be made payable
5. The address to which the reimbursement will be sent
6. The traveler's phone number

20.8.B Receipts

The expense report must have original receipts for expenses attached. Off-site OPTN members may submit scanned copies of the original receipts. If one traveler has a meal receipt that includes other OPTN Contractor travelers, the receipt must include the names of all travelers.

At-a-Glance

Clarification of Multi-Organ Policies

- **Affected/Proposed Policy:** Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates).

- **Policy Oversight Committee (POC)**

  Approximately 1,452 multi-organ transplants are performed each year. OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent. The organ–specific Committees are addressing multi-organ allocation issues, but the POC identified general multi-organ policies that could be clarified to support the organ-specific Committees' work, yet not interfere with the allocation issues and related language that they are addressing.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Compliance with OPTN Strategic Plan and Final Rule**
  By clarifying and reorganizing these policies, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. Since it will also enhance understanding and compliance, the proposed improvements to policy language could increase patient safety.

- **Specific Requests for Comment**
  The Committee invites comment on whether the proposed language is more easily understood. Additional input on whether this proposal supports current clinical practices is welcome.

Clarification of Multi-Organ Policies

Affected/Proposed Policy: Policies 2.12.F (Multiple Organ Procurement), 3.4.C (Candidate Registrations), 3.4.F (Multi-Organ Candidate Registrations), 5.4.D (Multiple Organ Procurement and Offers), 5.8 (Allocation of Multi-Organ Combinations), and 6.4.A (Waiting Time for Multi-organ Candidates).

Policy Oversight Committee (POC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

Approximately 1,452 multi-organ transplants were performed in 2013. OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent. The organ–specific Committees are addressing multi-organ allocation issues, but the POC identified general multi-organ policies that could be clarified to support the organ-specific Committees' work, yet not interfere with the allocation issues and related language that they are addressing. Specifically, the POC proposes these changes to policy language:

- Policy 2.12.F is edited for clarity and to better explain what is required when organs are recovered. This is *not* an issue of multi-organ procurement, but organ procurement in general, so the title is changed to reflect that. (Would appreciate thorough review from OPO folk in particular.)
- Information in Policy 3.4.F was similar in content with Policy 3.4.C therefore these two policies were combined. With these changes, Policy 3.4.C now includes the multi-organ candidate registration requirements so that all the information is in one place.
- Policy 5.4.D says the same thing as Policy 2.12.F and so it is deleted. The first sentence in the original language is vague— "OPO's medical judgment" and not a true requirement as written and therefore justifies deletion.
- The first sentence in Policy 5.8 is very similar to Policy 3.4.F and is not needed here.
- New section 5.8.A highlights different allocation scheme for Heart-Lung candidates and includes a cross-reference. This is not new, but it is moved out of the paragraph below for emphasis.
- New section 5.8.B clarifies multi-organ allocation and eliminates the language about paybacks that was not a true requirement and only "recommended" and is in keeping with the removal of paybacks once the new Kidney Allocation System (KAS) is implemented.
- Policy 6.4.A is better located in Policy 3.7 with the other waiting time modifications as new Policy 3.7.C. Table 6-4 is updated since most of these waiting time modifications cannot operationally be done since this is currently not programmed and there is currently no automated process to do these modifications. In addition, status to different organ types cannot transfer. For example, no way to equate a status 1a heart candidate's time to an LAS score, so these sorts of waiting time modifications do not logically make sense and have never been put into practice as currently written.

Background and Significance of the Proposal:

OPTN Policies regarding multi-organ procurement, allocation, and waiting time are unclear and sometimes inconsistent.

- **Collaboration:** The POC formed a multi-organ policies working group with representatives from the Thoracic, Kidney, Liver, and Pancreas Committees that drafted the new proposed policy language.

- **Alternatives considered:** The Committee explored the idea of waiting and addressing these issues as part of the projects the organ-specific Committees are working on to address multi-organ allocation issues. However, the POC recognized that having clearer and well-organized policies regarding multi-organ transplantation generally would help these Committees with their projects and therefore there was no need to wait.

- **Strengths and weaknesses:** This proposal's strength is that it clarifies these important policies that deal with multi-organ transplantation.

- **Description of intended and unintended consequences:** An intended consequence of the Committee is that these clarifies policies will support the organ-specific Committees in their projects concerning the specific multi-organ allocation policy issues that they are working to address.

Supporting Evidence and/or Modeling:

The 2013 OPTN Policies Plain Language Rewrite identified issues with the current multi-organ policies and highlighted the need to clarify these policies. While working to clarify the language in these policies, staff was able to identify improvements in organization as well.

Expected Impact on Living Donors or Living Donation:

This proposed policy change will not directly impact living donors or living donation.

Expected Impact on Specific Patient Populations:

This proposed policy change will not directly impact any specific patient population.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

By clarifying the definition for organ transplant and the start and end of transplant, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. Since it will also enhance reporting of transplant procedures and increase accuracy of reporting, the proposed improvements to policy language could increase patient safety.

Plan for Evaluating the Proposal:

The Committee will continue communication with UNOS staff to determine if members have questions or concerns about the new policy language.

Additional Data Collection:

There is no additional data collection required as a result of this policy change.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and, if approved, the clarified policies will become effective in September 2015.

Communication and Education Plan:

This proposal only clarifies and reorganizes current policy language and does not require that members change how they currently deal with multi-organ transplantation at their institutions. The following Communication & Education Activities will help notify members of the clarified policy language:

- Policy notice
- Presentation at Regional Meetings

Compliance Monitoring:

This proposal does not require any changes to the current compliance monitoring of these policy requirements.

Policy or Bylaw Proposal:

2.15.F ~~Multiple~~ Start Time for Organ Procurement

After ~~a member indicates its initial acceptance of an~~ organs have been offered and accepted, ~~the transplant hospitals and OPOs involved~~ recovery teams must agree on the time the ~~that multiple organ~~ procurement will begin. If ~~the members~~ they cannot agree on the ~~procurement~~ start time for the procurement, the host OPO has the authority to ~~may~~ withdraw the offer from the transplant hospital ~~or OPO~~ that cannot ~~unable to~~ agree on the start time for procurement ~~to begin~~.

3.4.C Candidate Registrations

Recipients of deceased and living donor organs must be registered as candidates on the waiting list prior to their transplant, including recipients receiving directed donations from deceased donors. All multi-organ candidates must be registered on the waiting list for each required organ.

Transplant programs must complete all candidate registrations, modifications, and removals in the waiting list.

3.4.D Candidate Human Leukocyte Antigen (HLA) Requirements

The candidate's transplant program must report to the OPTN Contractor complete human leukocyte antigen (HLA) information (at least 1A, 1B, and 1DR antigen) according to *Table 3-1* below:

Table 3-1: HLA Requirements

If the candidate is registered for a…	Then, HLA information is…
Kidney alone	Required
Kidney–pancreas	Required
Kidney with any other non-renal organ	Not required
Pancreas alone	Required

Transplant programs must report this HLA information using current World Health Organization (WHO) nomenclature when the candidate is registered on the waiting list.

3.4.E Inactive Status

If the candidate is temporarily unsuitable for transplant, then the candidate's transplant program may classify the candidate as inactive and the candidate will not receive any organ offers.

~~3.4.F Multi-organ Candidate Registrations~~

~~If a multi-organ transplant candidate requires a heart, lung, or liver the candidate must register on the waiting list separately for each required organ.~~

~~Multi-organ candidates who have been named as the recipient of a directed organ donation must appear on at least one of the deceased donor's match runs for at least one of the required organ types.~~

3.4.~~G~~F Multiple Transplant Program Registrations

Candidates may be registered for an organ at multiple transplant programs within the same Donation Service Area (DSA) or different DSAs. A transplant program may choose whether or not to accept a candidate seeking multiple registrations for an organ.

Transplant hospitals may access a report from the OPTN Contractor that identifies any candidates that have multiple registrations for the same organ. This report will not include the identities of the other hospitals where the candidates are registered.

Policy 3.7.C~~6.4.A~~ Waiting Time Modifications for Heart, Lung, and Heart-Lung Candidates

A transplant program may request that the OPTN Contractor modify a candidate's waiting time when a candidate has multiple registrations ~~qualifies to receive waiting time accrued from one waiting list to another waiting list~~ according to *Table ~~6-4~~* 3-6 below.

Table ~~6-4~~ 3-6: Waiting Time Modifications for Heart, Lung, and Heart-Lung Candidates

From this registration:	To this registration:
~~Heart~~	~~Lung~~
Heart	Heart-lung
~~Lung~~	~~Heart~~
~~Lung~~	~~Heart-lung~~
Heart-lung	Heart
Heart-lung	Lung

~~**5.4.D Multiple Organ Procurement and Offers**~~

~~If an OPO has permission to procure all organs from a deceased donor, that OPO must offer those organs unless, in the OPO's medical judgment, the organs are not suitable for transplant.~~

~~After the organs have been accepted, all receiving transplant hospitals must agree on when the multiple organ procurement will begin. If they cannot agree on a start time for the procurement, the host OPO may withdraw the offer from the transplant hospitals that accepted the organs.~~

5.4.~~E~~D Backup Organ Offers

OPOs may make backup offers for all organs. Transplant hospitals must treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ. If a transplant hospital refuses to consider or does not respond to a backup offer, the offer will be considered refused.

If a transplant hospital accepts a backup offer, it may later refuse to accept the organ based on medical or logistical criteria. Transplant hospitals should be promptly notified of any change in deceased donor status or organ availability.

5.4.~~F~~E Allocation to Candidates Not on the Match Run

When a candidate does not appear on at least one of the deceased donor's match runs for at least one organ type, the transplant hospital must document the reason the candidate does not appear and ensure that the organ is safe and appropriate for the candidate. Acceptable reasons for allocation to the candidate may include, but are not limited to, directed donations or to prevent organ waste.

In such an event, the transplant hospital must document *all* of the following:

1. The reason for transplanting an organ into a candidate who did not appear on the match run
2. The reason the candidate did not appear on the match run
3. Whether the transplant hospital is willing to accept a kidney from a deceased donor with a KDPI score greater than 85% or from a donation after circulatory death (DCD) donor, if applicable
4. That the transplant hospital verified the medical suitability between the deceased donor organ and recipient prior to transplant in at least, but not limited to, *all* the following areas according to organ type:

    - Blood type
    - Blood subtype, when used for allocation
    - Donor HLA and candidate's unacceptable antigens
    - Donor height
    - Donor weight
    - Infectious disease test results

The transplant hospital must maintain all related documentation.

5.4.~~G~~F Local Conflicts

If any member believes there is an inequity or has a conflict with an OPO policy regarding the allocation of organs that cannot be resolved, the member may submit the issue to the appropriate organ-specific committee and Board of Directors for review and a final decision.

Policy 5.8 Allocation of Multi-Organ Combinations

~~Candidates registered for multiple organs must appear on the heart, lung, or liver match run to be eligible to receive a heart, lung, or liver.~~

5.8.A Allocation of Heart-Lungs

Heart-lung combinations are allocated according to *Policy 6.5.E: Allocation of Heart-Lungs*.

5.8.B Other Multi-Organ Combinations

When multi-organ candidates ~~other than heart-lung candidates~~ are registered on the ~~eligible to receive a~~ heart, lung, or liver waiting list, the second required organ will be allocated to the multi-organ candidate from the same donor if the donor's DSA is the same DSA where the multi-organ candidate is registered. ~~Heart-lung combinations are allocated according to *Policy 6.5.E: Allocation of Heart-Lungs*.~~

If the multi-organ candidate is on a waiting list outside the donor's DSA, it is permissible to allocate the ~~voluntary sharing of the~~ second organ to the multi-organ candidate ~~is~~ receiving the first organ. ~~recommended. When the second organ is shared, the same organ of an identical blood type must be paid back to the host OPO from the next acceptable donor procured by the recipient OPO, unless the second organ is a kidney. If the second organ is a kidney, then there is no payback obligation.~~

At-a-Glance

Proposal to Clarify Definition of Organ Transplant and Transplant Date

- **Affected/Proposed Policy:** Policy 1.2: Definitions

- **Policy Oversight Committee (POC)**

  UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what should be reported as the transplant date, especially in regards to meeting reporting requirements in UNet[SM]. Members report that there is a disconnect in current definitions and actual clinical practices, and these proposed definitions will help bridge the disconnect and clarify the policy requirements.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Compliance with OPTN Strategic Plan and Final Rule**
  By clarifying the definition for organ transplant and the start and end of transplant, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. This proposal also supports the specific strategy to improve readability of OPTN rules and requirements. Since it will also enhance reporting of transplant procedures and increase accuracy of reporting, the proposed improvements to policy language could increase patient safety.

- **Specific Requests for Comment**
  The Committee invites comment on whether the proposed language clarifies transplant date as well as the start and end of the transplant procedure for reporting and removal of candidates from the waiting list. Additional input on whether this proposal supports current clinical practices is welcome.

Proposal to Clarify Definition of Organ Transplant and Transplant Date

Affected/Proposed Policy: Policy 1.2: Definitions

Policy Oversight Committee (POC)

Public comment response period: September 29 – December 5, 2014

Summary and Goals of the Proposal:

UNOS staff routinely receives questions from OPTN/UNOS members about the definition of organ transplant, including what should be reported as the transplant date, especially in regards to meeting reporting requirements in UNet^{SM}. Members report that there is a disconnect between the current definitions and actual clinical practices, and these proposed definitions will help bridge the disconnect and clarify the policy requirements.

Background and Significance of the Proposal:

UNOS staff receives numerous questions about how to report the start and end date of transplant. This proposal aims to clarify this so that OPTN members can effectively meet reporting requirements in UNet^{SM}.

- **Collaboration:** UNOS staff collaborated to identify the problem with the current definitions of organ transplant and transplant date as reported by our members. A major concern of staff and POC was to ensure that we did not unknowingly affect other policies or reporting requirements when we changed these definitions. Therefore a workgroup of the POC discussed all of the situations in policy where transplant dates are relevant. The POC, which is made up with representatives from all the OPTN/UNOS Committees, reviewed and approved the final policy proposal.

- **Alternatives considered:** The Committee explored the idea of combining the two separate definitions, if possible, but decided that both were required since having a separate definition for transplant date clarifies the reporting requirements. The two definitions ensure that data reported to the OPTN reflect what actually happens in a single-organ or a multi-organ transplant. The definition for organ transplant focuses on both when the transplant begins (at anastomosis of *that* organ), and an organ transplant is complete (when the cavity is closed and final stitch or staple applied or when the recipient leaves the OR). The definition for *transplant date* requires that the transplant date for an organ would be determined by the start of anastomosis for each organ, so you could have a multi-organ transplant occur on two different days.

- **Description of intended and unintended consequences:** The Committee and UNOS staff carefully considered whether changing these definitions would affect other policies in an unintended way, and they could find no other areas in current policy that would be affected by the change.

Supporting Evidence and/or Modeling:

For reporting date of transplant and the subsequent removal of candidates from the waiting list, members often have questions about the exact date to report for the start of a transplant

procedure and the end of a transplant procedure. A majority of the questions focus on how current clinical practice is sometimes out of sync with the current definitions in OPTN Policy.

The following two scenarios present the most common concerns and questions:

1. A candidate received a liver transplant but the organ was larger than expected, so the surgical team did not immediately close the abdomen. The patient is removed from the operating room and subsequently dies three days later. Per current policy, the transplant was not complete until the abdominal cavity was closed; therefore, the candidate would remain on the waiting list for those intervening three days until removed using removal code 21 – *died during the transplant procedure*.

   POC members discussed a common practice for candidates to be packed with sterile mesh in order to allow for post-transplant intervention and removed from the operating room. Once the immediate concern has passed, the candidate returns to the operating room for placement of the final stitch. By clinical standards, POC members agreed that the transplant concluded when the candidate originally left the operating room, but the policy requirement was not met due to the absence of the final stitch.

   These cases show the need for clarification of when a transplant procedure officially ends, and the addition of language to provide for the end of transplant once the candidate leaves the operating room, regardless of whether or not the final stitch is completed, will clarify this issue.

2. In the case of a multi-organ transplant, a recipient leaves the operating room after receiving the first organ transplant and then returns to the operating room on the next day to receive a second organ from the same donor. Per current policy, the date of transplant for the second organ is recorded as the date of the first organ's anastomosis, which occurred more than 24 hours prior.

   The evolving clinical practice of a time lapse between individual organ transplants during a multi-organ procedure is not addressed in current policy. Current policy states: *For a multi-organ transplant procedure, the transplant date for each organ is determined by the transplant date of the first organ transplanted.* In order to comply with the requirement to remove a patient from the waiting list within 24 hours of transplant, the transplant hospital would need to remove a patient from an organ's waiting list prior to the patient receiving that organ, since the clock starts to tick when the first organ is transplanted, regardless of the organs that follow.

A subcommittee of the POC was convened to discuss these issues and recurring questions. They concluded that the current definitions do not provide a reporting mechanism for a transplant hospital to accurately report the events described above. This proposal offers revisions to policy that:

- Maintain the current reporting elements while capturing existing clinical practice
- Ensure data reported to the OPTN reflect what actually happens in a single-organ or multi-organ transplant

Expected Impact on Living Donors or Living Donation:

This proposed policy change will change the required reporting date of transplant for living donors.

Expected Impact on Specific Patient Populations:

This proposed policy change will not directly impact any specific patient population.

Expected Impact on OPTN Strategic Plan, and Adherence to OPTN Final Rule:

By clarifying the definition for organ transplant and the start and end of transplant, the proposal supports the strategic plan goal to promote the efficient management of the OPTN. This proposal also supports the specific strategy to improve readability of OPTN rules and requirements. Since it will also enhance reporting of transplant procedures and increase accuracy of reporting, the proposed improvements to policy language could increase patient safety.

Plan for Evaluating the Proposal:

The Committee will continue to communicate with staff to determine if members continue to have questions and concerns when reporting the transplant date to the OPTN and complying with timely removal of candidates from the organ waiting list.

Additional Data Collection:

There is no additional data collection required as a result of this policy change. The proposal will help support more accurate reporting of transplant date and may help members comply with candidate removal from the waiting list requirements.

Expected Implementation Plan:

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in June, 2015 and, if approved, the clarified definitions will become effective pending programming.

Communication and Education Plan:

This proposal may require that members change how they currently report transplant date and remove candidates from the waiting list. The following Communication & Education Activities will help notify members of the clarified definitions:

- Policy notice
- Online article
- Presentation at Regional Meetings

Compliance Monitoring:

Members will be expected to accurately report data based on the proposed language. Although the proposed language will not change the fields routinely monitored, members will be expected to apply the new definitions of organ transplant and transplant date when reporting in UNet^{SM}. Any data entered in UNet^{SM} may be subject to OPTN review, and members are required to provide documentation as requested.

Policy or Bylaw Proposal:

1.2: Definitions

Organ transplant
Organ transplants include solid organ transplants and islet infusions. An organ transplant ~~B~~begins at the start of ~~once any initiation of~~ organ anastomosis ~~has taken place during the intended transplant~~ or the start of an islet ~~cell~~ infusion. An organ transplant ~~procedure~~ is complete when ~~*either*~~ *any* of the following occurs:

- The chest or abdominal cavity is closed and the final skin stitch or staple is applied.
- The transplant recipient leaves the operating room, even if the chest or abdominal cavity cannot be closed.
- The islet ~~cell~~ infusion is complete.

Transplant date
Determined by the start of the organ anastomosis during transplant or the start of the islet infusion. ~~beginning of organ anastomosis~~. ~~For a multi-organ transplant procedure, the transplant date for each organ is determined by the transplant date of the first organ transplanted.~~